DIMETHYL FUMARATE - dimethyl fumarate DIMETHYL FUMARATE- dimethyl fumarate capsule, delayed release Lupin Pharmaceuticals, Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Dimethyl Fumarate Delayed-Release Capsules safely and effectively. See full prescribing information for Dimethyl Fumarate Delayed-Release Capsules. DIMETHYL FUMARATE delayed-release capsules, for oral use Initial U.S. Approval: 2013

..... INDICATIONS AND USAGE Dimethyl fumarate is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults (1)

DOSAGE AND ADMINISTRATION

- Starting dose: 120 mg twice a day, orally, for 7 days (2.1)
- Maintenance dose after 7 days: 240 mg twice a day, orally (2.1)
- · Swallow dimethyl fumarate capsules whole and intact. Do not crush, chew, or sprinkle capsule contents on food (2.1)
- Take dimethyl fumarate delayed-release capsules with or without food (2.1)

DOSAGE FORMS AND STRENGTHS Delayed-release capsules: 120 mg and 240 mg (3)

..... CONTRAINDICATIONS Known hypersensitivity to dimethyl fumarate or any of the excipients of dimethyl fumarate delayed-release capsules. (4)

WARNINGS AND PRECAUTIONS • Anaphylaxis and angioedema: Discontinue and do not restart dimethyl fumarate if these occur. (5.1)

- · Progressive multifocal leukoencephalopathy (PML): Withhold dimethyl fumarate at the first sign or symptom suggestive of PML. (5.2)
- Herpes zoster and other serious opportunistic infections: Consider withholding dimethyl fumarate in cases of serious infection until the infection has resolved. (5.3)
- Lymphopenia: Obtain a CBC including lymphocyte count before initiating dimethyl fumarate, after 6 months, and every 6 to 12 months thereafter. Consider interruption of dimethyl fumarate if lymphocyte counts <0.5 x 10⁹/L persist for more than six months. (5.4)
- Liver injury: Obtain serum aminotransferase, alkaline phosphatase, and total bilirubin levels before initiating dimethyl fumarate and during treatment, as clinically indicated. Discontinue dimethyl fumarate if clinically significant liver injury induced by dimethyl fumarate is suspected. (5.5)

ADVERSE REACTIONS Most common adverse reactions (incidence \geq 10% and \geq 2% placebo) were flushing, abdominal pain, diarrhea, and nausea. (6.1) To report SUSPECTED ADVERSE REACTIONS, contact Lupin Pharmaceuticals, Inc. at 1-800-

399-2561 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. USE IN SPECIFIC POPULATIONS -----

Pregnancy: Based on animal data, may cause fetal harm. (8.1) See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling. Revised: 4/2021

FULL PRESCRIBING INFORMATION: CONTENTS* 1 INDICATIONS AND USAGE

2 DOSAGE AND ADMINISTRATION

- 2.1 Dosing Information
- 2.2 Blood Tests Prior to Initiation of Therapy
- **3 DOSAGE FORMS AND STRENGTHS**
- **4 CONTRAINDICATIONS**

5 WARNINGS AND PRECAUTIONS

- 5.1 Anaphylaxis and Angioedema
- 5.2 Progressive Multifocal Leukoencephalopathy
- 5.3 Herpes Zoster and Other Serious Opportunistic Infections
- 5.4 Lymphopenia
- 5.5 Liver Injury
- 5.6 Flushing

6 ADVERSE REACTIONS

- 6.1 Clinical Trials Experience
- 6.2 Postmarketing Experience

8 USE IN SPECIFIC POPULATIONS

- 8.1 Pregnancy
- 8.2 Lactation
- 8.4 Pediatric Use
- 8.5 Geriatric Use

10 OVERDOSE

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY

- 12.1 Mechanism of Action
 - 12.2 Pharmacodynamics
 - 12.3 Pharmacokinetics

13 NONCLINICAL TOXICOLOGY

- 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
- 13.2 Animal Toxicology and/or Pharmacology

14 CLINICAL STUDIES

16 HOW SUPPLIED/STORAGE AND HANDLING

- **17 PATIENT COUNSELING INFORMATION**
- * Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Dimethyl fumarate is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

2 DOSAGE AND ADMINISTRATION

2.1 Dosing Information

The starting dose for dimethyl fumarate delayed-release capsule is 120 mg twice a day orally. After 7 days, the dose should be increased to the maintenance dose of 240 mg twice a day orally. Temporary dose reductions to 120 mg twice a day may be considered for individuals who do not tolerate the maintenance dose. Within 4 weeks, the recommended dose of 240 mg twice a day should be resumed. Discontinuation of dimethyl fumarate delayed-release capsules should be considered for patients unable to tolerate return to the maintenance dose. The incidence of flushing may be reduced by administration of dimethyl fumarate delayed-release capsules with food. Alternatively, administration of non-enteric coated aspirin (up to a dose of 325 mg) 30 minutes prior to dimethyl fumarate delayed-release capsules dosing may reduce the incidence or severity of flushing [see CLINICAL PHARMACOLOGY (12.3)].

Dimethyl fumarate delayed-release capsules should be swallowed whole and intact. Dimethyl fumarate delayed-release capsules should not be crushed or chewed and the capsule contents should not be sprinkled on food. Dimethyl fumarate delayed-release capsules can be taken with or without food.

2.2 Blood Tests Prior to Initiation of Therapy

Obtain a complete blood cell count (CBC) including lymphocyte count before initiation of therapy [see WARNINGS AND PRECAUTIONS (5.4)].

Obtain serum aminotransferase, alkaline phosphatase, and total bilirubin levels prior to treatment with dimethyl fumarate delayed-release capsules [see WARNINGS AND PRECAUTIONS (5.5)].

3 DOSAGE FORMS AND STRENGTHS

Dimethyl fumarate delayed-release capsules are available as hard gelatin delayed-release capsules containing 120 mg or 240 mg of dimethyl fumarate. The 120 mg capsules have a yellow cap and white body imprinted with circular LU on cap and D76 on body. The 240 mg capsules have a yellow cap and body imprinted with circular LU on cap and D77 on body.

4 CONTRAINDICATIONS

Dimethyl fumarate delayed-release capsules are contraindicated in patients with known hypersensitivity to dimethyl fumarate or to any of the excipients of dimethyl fumarate delayed-release capsules. Reactions have included anaphylaxis and angioedema [see WARNINGS AND PRECAUTIONS (5.1)].

5 WARNINGS AND PRECAUTIONS

5.1 Anaphylaxis and Angioedema

Dimethyl fumarate can cause anaphylaxis and angioedema after the first dose or at any time during treatment. Signs and symptoms have included difficulty breathing, urticaria, and swelling of the throat and tongue. Patients should be instructed to discontinue dimethyl fumarate and seek immediate medical care should they experience signs and symptoms of anaphylaxis or angioedema.

5.2 Progressive Multifocal Leukoencephalopathy

Progressive multifocal leukoencephalopathy (PML) has occurred in patients with MS treated with dimethyl fumarate. PML is an opportunistic viral infection of the brain caused by the JC virus (JCV) that typically only occurs in patients who are immunocompromised, and that usually leads to death or severe disability. A fatal case of PML occurred in a patient who received dimethyl fumarate for 4 years while enrolled in a clinical trial. During the clinical trial, the patient experienced prolonged lymphopenia (lymphocyte counts predominantly <0.5x10⁹/L for 3.5 years) while taking dimethyl fumarate [see WARNINGS AND PRECAUTIONS (5.4)]. The patient had no other identified systemic medical conditions resulting in compromised immune system function and had not previously been treated with natalizumab, which has a known association with PML. The patient was also not taking any immunosuppressive or immunomodulatory medications concomitantly.

PML has also occurred in the postmarketing setting in the presence of lymphopenia (< 0.9 x 10⁹/L). While the role of lymphopenia in these cases is uncertain, the PML cases have occurred predominantly in patients with lymphocyte counts < 0.8 x 10⁹/L

persisting for more than 6 months.

At the first sign or symptom suggestive of PML, withhold dimethyl fumarate and perform an appropriate diagnostic evaluation. Typical symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes.

MRI findings may be apparent before clinical signs or symptoms. Cases of PML, diagnosed based on MRI findings and the detection of JCV DNA in the cerebrospinal fluid in the absence of clinical signs or symptoms specific to PML, have been reported in patients treated with other MS medications associated with PML. Many of these patients subsequently became symptomatic with PML. Therefore, monitoring with MRI for signs that may be consistent with PML may be useful, and any suspicious findings should lead to further investigation to allow for an early diagnosis of PML, if present. Lower PML-related mortality and morbidity have been reported following discontinuation of another MS medication associated with PML who were initially asymptomatic compared to patients with PML who had characteristic clinical signs and symptoms at diagnosis. It is not known whether these differences are due to early detection and discontinuation of MS treatment or due to differences in disease in these patients.

5.3 Herpes Zoster and Other Serious Opportunistic Infections

Serious cases of herpes zoster have occurred with dimethyl fumarate, including disseminated herpes zoster, herpes zoster ophthalmicus, herpes zoster meningoencephalitis, and herpes zoster meningomyelitis. These events may occur at any time during treatment. Monitor patients on dimethyl fumarate for signs and symptoms of herpes zoster. If herpes zoster occurs, appropriate treatment for herpes zoster should be administered.

Other serious opportunistic infections have occurred with dimethyl fumarate, including cases of serious viral (herpes simplex virus, West Nile virus, cytomegalovirus), fungal (Candida and Aspergillus), and bacterial (Nocardia, Listeria monocytogenes, Mycobacterium tuberculosis) infections. These infections have been reported in patients with reduced absolute lymphocyte counts (ALC) as well as in patients with normal ALC. These infections have affected the brain, meninges, spinal cord, gastrointestinal tract, lungs, skin, eye, and ear. Patients with symptoms and signs consistent with any of these infections should undergo prompt diagnostic evaluation and receive appropriate treatment.

Consider withholding dimethyl fumarate treatment in patients with herpes zoster or other serious infections until the infection has resolved [see ADVERSE REACTIONS (6.2)].

5.4 Lymphopenia

Dimethyl fumarate may decrease lymphocyte counts. In the MS placebo controlled trials, mean lymphocyte counts decreased by approximately 30% during the first year of treatment with dimethyl fumarate and then remained stable. Four weeks after stopping dimethyl fumarate, mean lymphocyte counts increased but did not return to baseline. Six percent (6%) of dimethyl fumarate patients and <1% of placebo patients experienced lymphocyte counts $<0.5 \times 10^9/L$ (lower limit of normal $0.91 \times 10^9/L$). The incidence of infections (60% vs 58%) and serious infections (2% vs 2%) was similar in patients treated with dimethyl fumarate or placebo, respectively. There was no increased incidence of serious infections observed in patients with lymphocyte counts $<0.8 \times 10^9/L$ or $<0.5 \times 10^9/L$ in controlled trials, although one patient in an extension study developed PML in the setting of prolonged lymphopenia (lymphocyte counts (5.2)].

In controlled and uncontrolled clinical trials, 2% of patients experienced lymphocyte counts <0.5 x $10^9/L$ for at least six months, and in this group the majority of lymphocyte counts remained < $0.5 \times 10^9/L$ with continued therapy. Dimethyl fumarate has not been studied in patients with preexisting low lymphocyte counts.

Obtain a CBC, including lymphocyte count, before initiating treatment with dimethyl fumarate, 6 months after starting treatment, and then every 6 to 12 months thereafter, and as clinically indicated. Consider interruption of dimethyl fumarate in patients with lymphocyte counts less than 0.5 x 10^9 /L persisting for more than six months. Given the potential for delayed recovery of lymphocyte counts, continue to obtain lymphocyte counts until their recovery if dimethyl fumarate is discontinued or interrupted due to lymphopenia. Consider withholding treatment from patients with serious infections until resolution. Decisions about whether or not to restart dimethyl fumarate should be individualized based on clinical circumstances.

5.5 Liver Injury

Clinically significant cases of liver injury have been reported in patients treated with dimethyl fumarate in the postmarketing setting. The onset has ranged from a few days to several months after initiation of treatment with dimethyl fumarate. Signs and symptoms of liver injury, including elevation of serum aminotransferases to greater than 5-fold the upper limit of normal and elevation of total bilirubin to greater than 2-fold the upper limit of normal and elevation. These abnormalities resolved upon treatment discontinuation. Some cases required hospitalization. None of the reported cases resulted in liver failure, liver transplant, or death. However, the combination of new serum aminotransferase elevations with increased levels of bilirubin caused by drug-induced hepatocellular injury is an important predictor of serious liver injury that may lead to acute liver failure, liver transplant, or death in some patients.

Elevations of hepatic transaminases (most no greater than 3 times the upper limit of

normal) were observed during controlled trials [see ADVERSE REACTIONS (6.1)].

Obtain serum aminotransferase, alkaline phosphatase (ALP), and total bilirubin levels prior to treatment with dimethyl fumarate and during treatment, as clinically indicated. Discontinue dimethyl fumarate if clinically significant liver injury induced by dimethyl fumarate is suspected.

5.6 Flushing

Dimethyl fumarate may cause flushing (e.g., warmth, redness, itching, and/or burning sensation). In clinical trials, 40% of dimethyl fumarate treated patients experienced flushing. Flushing symptoms generally began soon after initiating dimethyl fumarate and usually improved or resolved over time. In the majority of patients who experienced flushing, it was mild or moderate in severity. Three percent (3%) of patients discontinued dimethyl fumarate for flushing and <1% had serious flushing symptoms that were not life-threatening but led to hospitalization. Administration of dimethyl fumarate with food may reduce the incidence of flushing. Alternatively, administration of non-enteric coated aspirin (up to a dose of 325 mg) 30 minutes prior to dimethyl fumarate dosing may reduce the incidence or severity of flushing *[see DOSING AND ADMINISTRATION (2.1) AND CLINICAL PHARMACOLOGY (12.3)]*.

6 ADVERSE REACTIONS

The following important adverse reactions are described elsewhere in labeling:

- Anaphylaxis and Angioedema [see WARNINGS AND PRECAUTIONS (5.1)].
- Progressive multifocal leukoencephalopathy [see WARNINGS AND PRECAUTIONS (5.2)].
- Herpes Zoster and Other Serious Opportunistic Infections [see WARNINGS AND PRECAUTIONS (5.3)].
- Lymphopenia [see WARNINGS AND PRECAUTIONS (5.4)].
- Liver Injury [see WARNINGS AND PRECAUTIONS (5.5)].
- Flushing [see WARNINGS AND PRECAUTIONS (5.6)].

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

The most common adverse reactions (incidence \geq 10% and \geq 2% more than placebo) for dimethyl fumarate were flushing, abdominal pain, diarrhea, and nausea.

Adverse Reactions in Placebo-Controlled Trials

In the two well-controlled studies demonstrating effectiveness, 1529 patients received dimethyl fumarate with an overall exposure of 2244 person-years [see CLINICAL STUDIES (14)].

The adverse reactions presented in the table below are based on safety information from 769 patients treated with dimethyl fumarate 240 mg twice a day and 771 placebo-treated patients.

Table 1: Adverse Reactions in Study 1 and 2 reported for dimethyl fumarate
240 mg BID at \geq 2% higher incidence than placebo

	Dimethyl FumarateN=769 %	Placebo N=771 %
Flushing	40	6
Abdominal pain	18	10
Diarrhea	14	11
Nausea	12	9
Vomiting	9	5
Pruritus	8	4
Rash	8	3
Albumin urine present	6	4
Erythema	5	1
Dyspepsia	5	3
Aspartate aminotransferase increased	4	2
Lymphopenia	2	<1

Gastrointestinal:

Dimethyl fumarate caused GI events (e.g., nausea, vomiting, diarrhea, abdominal pain, and dyspepsia). The incidence of GI events was higher early in the course of treatment (primarily in month 1) and usually decreased over time in patients treated with dimethyl fumarate compared with placebo. Four percent (4%) of patients treated with dimethyl fumarate and less than 1% of placebo patients discontinued due to gastrointestinal events. The incidence of serious GI events was 1% in patients treated with dimethyl fumarate.

Hepatic Transaminases:

An increased incidence of elevations of hepatic transaminases in patients treated with dimethyl fumarate was seen primarily during the first six months of treatment, and most patients with elevations had levels < 3 times the upper limit of normal (ULN) during controlled trials. Elevations of alanine aminotransferase and aspartate aminotransferase to \geq 3 times the ULN occurred in a small number of patients treated with both dimethyl

fumarate and placebo and were balanced between groups. There were no elevations in transaminases \geq 3 times the ULN with concomitant elevations in total bilirubin > 2 times the ULN. Discontinuations due to elevated hepatic transaminases were < 1% and were similar in patients treated with dimethyl fumarate or placebo.

Eosinophilia:

A transient increase in mean eosinophil counts was seen during the first 2 months of therapy.

Adverse Reactions in Placebo-Controlled and Uncontrolled Studies

In placebo-controlled and uncontrolled clinical studies, a total of 2513 patients have received dimethyl fumarate and been followed for periods up to 4 years with an overall exposure of 4603 person-years. Approximately 1162 patients have received more than 2 years of treatment with dimethyl fumarate. The adverse reaction profile of dimethyl fumarate in the uncontrolled clinical studies was consistent with the experience in the placebo-controlled clinical trials.

6.2 Postmarketing Experience

The following adverse reaction has been identified during post approval use of dimethyl fumarate. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Liver function abnormalities (elevations in transaminases \geq 3 times ULN with concomitant elevations in total bilirubin > 2 times ULN) have been reported following dimethyl fumarate administration in postmarketing experience [See WARNINGS AND PRECAUTIONS (5.5)].

Herpes zoster infection and other serious opportunistic infections have has been reported with dimethyl fumarate administration in postmarketing experience [See WARNINGS AND PRECAUTIONS (5.3)].

Rhinorrhea has been reported with Dimethyl Fumarate Delayed-Release Capsules administration in post marketing experience.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate data on the developmental risk associated with the use of dimethyl fumarate in pregnant women. In animals, adverse effects on offspring survival, growth, sexual maturation, and neurobehavioral function were observed when dimethyl

fumarate (DMF) was administered during pregnancy and lactation at clinically relevant doses [see Data].

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively. The background risk of major birth defects and miscarriage for the indicated population is unknown.

Data

Animal Data

In rats administered DMF orally (25, 100, 250 mg/kg/day) throughout organogenesis, embryo fetal toxicity (reduced fetal body weight and delayed ossification) were observed at the highest dose tested. This dose also produced evidence of maternal toxicity (reduced body weight). Plasma exposure (AUC) for monomethyl fumarate (MMF), the major circulating metabolite, at the no effect dose is approximately three times that in humans at the recommended human dose (RHD) of 480 mg/day. In rabbits administered DMF orally (25, 75, and 150 mg/kg/day) throughout organogenesis, embryo lethality and decreased maternal body weight were observed at the highest dose tested. The plasma AUC for MMF at the no-effect dose is approximately 5 times that in humans at the RHD.

Oral administration of DMF (25, 100, and 250 mg/kg/day) to rats throughout organogenesis and lactation resulted in increased lethality, persistent reductions in body weight, delayed sexual maturation (male and female pups), and reduced testicular weight at the highest dose tested.

Neurobehavioral impairment was observed at all doses. A no-effect dose for developmental toxicity was not identified. The lowest dose tested was associated with plasma AUC for MMF lower than that in humans at the RHD.

8.2 Lactation

Risk Summary

There are no data on the presence of DMF or MMF in human milk. The effects on the breastfed infant and on milk production are unknown.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for dimethyl fumarate and any potential adverse effects on the breastfed infant from the drug or from the underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

Clinical studies of dimethyl fumarate did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients.

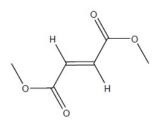
10 OVERDOSE

Cases of overdose with dimethyl fumarate have been reported. The symptoms described in these cases were consistent with the known adverse event profile of dimethyl fumarate.

There are no known therapeutic interventions to enhance elimination of dimethyl fumarate nor is there a known antidote. In the event of overdose, initiate symptomatic supportive treatment as clinically indicated.

11 DESCRIPTION

Dimethyl fumarate delayed-release capsule contains dimethyl fumarate which is also known by its chemical name, dimethyl (E) butenedioate, ($C_6H_8O_4$). It has the following structure:



Dimethyl fumarate is a white to off-white powder that is highly soluble in water with a molecular mass of 144.13.

Dimethyl fumarate delayed-release capsules are provided as hard gelatin delayed-release capsules for oral administration, containing 120 mg or 240 mg of dimethyl fumarate consisting of the following inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, methacrylic acid copolymer - Type A, methacrylic acid copolymer dispersion, silicified microcrystalline cellulose, talc and triethyl citrate. The capsule shell, printed with black ink, contains the following inactive ingredients: black iron oxide, D & C yellow 10, FD & C yellow 6, gelatin, potassium hydroxide, propylene glycol, shellac, strong ammonia solution and titanium dioxide.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The mechanism by which dimethyl fumarate (DMF) exerts its therapeutic effect in multiple sclerosis is unknown. DMF and the metabolite, monomethyl fumarate (MMF), have been shown to activate the Nuclear factor (erythroid-derived 2)-like 2 (Nrf2) pathway *in vitro* and *in vivo* in animals and humans. The Nrf2 pathway is involved in the cellular response to oxidative stress. MMF has been identified as a nicotinic acid receptor agonist *in vitro*.

12.2 Pharmacodynamics

Potential to prolong the QT interval

In a placebo controlled thorough QT study performed in healthy subjects, there was no evidence that dimethyl fumarate caused QT interval prolongation of clinical significance (i.e., the upper bound of the 90% confidence interval for the largest placebo-adjusted, baseline-corrected QTc was below 10 ms).

12.3 Pharmacokinetics

After oral administration of dimethyl fumarate, dimethyl fumarate undergoes rapid presystemic hydrolysis by esterases and is converted to its active metabolite, monomethyl fumarate (MMF). Dimethyl fumarate is not quantifiable in plasma following oral administration of dimethyl fumarate. Therefore all pharmacokinetic analyses related to dimethyl fumarate were performed with plasma MMF concentrations. Pharmacokinetic data were obtained in subjects with multiple sclerosis and healthy volunteers.

Absorption

The median T_{max} of MMF is 2 to 2.5 hours. The peak plasma concentration (C_{max}) and overall exposure (AUC) increased approximately dose proportionally in the dose range studied (120 mg to 360 mg). Following administration of dimethyl fumarate delayed-release capsules 240 mg twice a day with food, the mean C_{max} of MMF was 1.87 mg/L and AUC was 8.21 mg.hr/L in MS patients.

A high-fat, high-calorie meal did not affect the AUC of MMF but decreased its C_{max} by 40%. The T_{max} was delayed from 2.0 hours to 5.5 hours. In this study, the incidence of

flushing was reduced by approximately 25% in the fed state.

Distribution

The apparent volume of distribution of MMF varies between 53 and 73 L in healthy subjects. Human plasma protein binding of MMF is 27 to 45% and independent of concentration.

Metabolism

In humans, dimethyl fumarate is extensively metabolized by esterases, which are ubiquitous in the gastrointestinal tract, blood, and tissues, before it reaches the systemic circulation. Further metabolism of MMF occurs through the tricarboxylic acid (TCA) cycle, with no involvement of the cytochrome P450 (CYP) system. MMF, fumaric and citric acid, and glucose are the major metabolites in plasma.

Elimination

Exhalation of CO₂ is the primary route of elimination, accounting for approximately 60% of the dimethyl fumarate dose. Renal and fecal elimination are minor routes of elimination, accounting for 16% and 1% of the dose respectively. Trace amounts of unchanged MMF were present in urine.

The terminal half-life of MMF is approximately 1 hour and no circulating MMF is present at 24 hours in the majority of individuals. Accumulation of MMF does not occur with multiple doses of dimethyl fumarate.

Specific Populations

Body weight, gender, and age do not require dosage adjustment.

No studies have been conducted in subjects with hepatic or renal impairment. However, neither condition would be expected to affect exposure to MMF and therefore no dosage adjustment is necessary.

Drug Interaction Studies

No potential drug interactions with dimethyl fumarate or MMF were identified in *in vitro* CYP inhibition and induction studies, or in P-glycoprotein studies. Single doses of interferon beta-1a or glatiramer acetate did not alter the pharmacokinetics of MMF. Aspirin, when administered approximately 30 minutes before dimethyl fumarate, did not alter the pharmacokinetics of MMF.

Oral Contraceptives

The coadministration of dimethyl fumarate with a combined oral contraceptive (norelgestromin and ethinyl estradiol) did not elicit any relevant effects in oral contraceptives exposure. No interaction studies have been performed with oral contraceptives containing other progestogens.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Carcinogenicity studies of dimethyl fumarate (DMF) were conducted in mice and rats. In mice, oral administration of DMF (25, 75, 200, and 400 mg/kg/day) for up to two years resulted in an increase in nonglandular stomach (forestomach) and kidney tumors: squamous cell carcinomas and papillomas of the forestomach in males and females at 200 and 400 mg/kg/day; leiomyosarcomas of the forestomach at 400 mg/kg/day in males and females; renal tubular adenomas and carcinomas at 200 and 400 mg/kg/day in males; and renal tubule adenomas at 400 mg/kg/day in females. Plasma MMF exposure (AUC) at the highest dose not associated with tumors in mice (75 mg/kg/day) was similar to that in humans at the recommended human dose (RHD) of 480 mg/day.

In rats, oral administration of DMF (25, 50, 100, and 150 mg/kg/day) for up to two years resulted in increases in squamous cell carcinomas and papillomas of the forestomach at all doses tested in males and females, and in testicular interstitial (Leydig) cell adenomas at 100 and 150 mg/kg/day. Plasma MMF AUC at the lowest dose tested was lower than that in humans at the RHD.

Mutagenesis

Dimethyl fumarate (DMF) and monomethyl fumarate (MMF) were not mutagenic in the *in vitro* bacterial reverse mutation (Ames) assay. DMF and MMF were clastogenic in the *in vitro* chromosomal aberration assay in human peripheral blood lymphocytes in the absence of metabolic activation. DMF was not clastogenic in the *in vivo* micronucleus assay in the rat.

Impairment of Fertility

In male rats, oral administration of DMF (75, 250, and 375 mg/kg/day) prior to and throughout the mating period had no effect on fertility; however, increases in non-motile sperm were observed at the mid and high doses. The no-effect dose for adverse effects on sperm is similar to the recommended human dose (RHD) of 480 mg/day on a body surface area (mg/m²) basis.

In female rats, oral administration of DMF (20, 100, and 250 mg/kg/day) prior to and during mating and continuing to gestation day 7 caused disruption of the estrous cycle and increases in embryolethality at the highest dose tested. The highest dose not associated with adverse effects (100 mg/kg/day) is twice the RHD on a mg/m²basis.

Testicular toxicity (germinal epithelial degeneration, atrophy, hypospermia, and/or

hyperplasia) was observed at clinically relevant doses in mice, rats, and dogs in subchronic and chronic oral toxicity studies of DMF, and in a chronic oral toxicity study evaluating a combination of four fumaric acid esters (including DMF) in rats.

13.2 Animal Toxicology and/or Pharmacology

Kidney toxicity was observed after repeated oral administration of dimethyl fumarate (DMF) in mice, rats, dogs, and monkeys. Renal tubule epithelia regeneration, suggestive of tubule epithelial injury, was observed in all species. Renal tubular hyperplasia was observed in rats with dosing for up to two years. Cortical atrophy and interstitial fibrosis were observed in dogs and monkeys at doses above 5 mg/kg/day. In monkeys, the highest dose tested (75 mg/kg/day) was associated with single cell necrosis and multifocal and diffuse interstitial fibrosis, indicating irreversible loss of renal tissue and function. In dogs and monkeys, the 5 mg/kg/day dose was associated with plasma MMF exposures less than or similar to that in humans at the recommended human dose (RHD).

A dose-related increase in incidence and severity of retinal degeneration was observed in mice following oral administration of DMF for up to two years at doses above 75 mg/kg/day, a dose associated with plasma MMF exposure (AUC) similar to that in humans at the RHD.

14 CLINICAL STUDIES

The efficacy and safety of dimethyl fumarate delayed-release capsules were demonstrated in two studies (Studies 1 and 2) that evaluated dimethyl fumarate delayed-release capsules taken either twice or three times a day in patients with relapsing-remitting multiple sclerosis (RRMS). The starting dose for dimethyl fumarate delayed-release capsules was 120 mg twice or three times a day for the first 7 days, followed by an increase to 240 mg twice or three times a day. Both studies included patients who had experienced at least 1 relapse over the year preceding the trial or had a brain Magnetic Resonance Imaging (MRI) scan demonstrating at least one gadolinium-enhancing (Gd+) lesion within 6 weeks of randomization. The Expanded Disability Status Scale (EDSS) was also assessed and patients could have scores ranging from 0 to 5. Neurological evaluations were performed at baseline, every 3 months, and at the time of suspected relapse. MRI evaluations were performed at baseline, month 6, and year 1 and 2 in a subset of patients (44% in Study 1 and 48% in Study 2).

Study 1: Placebo-Controlled Trial in RRMS

Study 1 was a 2-year randomized, double-blind, placebo-controlled study in 1234 patients with RRMS. The primary endpoint was the proportion of patients relapsed at 2 years. Additional endpoints at 2 years included the number of new or newly enlarging T2 hyperintense lesions, number of new T1 hypointense lesions, number of Gd+ lesions, annualized relapse rate (ARR), and time to confirmed disability progression. Confirmed disability progression was defined as at least a 1 point increase from baseline EDSS (1.5 point increase for patients with baseline EDSS of 0) sustained for 12 weeks.

Patients were randomized to receive dimethyl fumarate delayed-release capsules 240 mg twice a day (n=410), dimethyl fumarate delayed-release capsules 240 mg three times a day (n=416), or placebo (n=408) for up to 2 years. The median age was 39 years, median time since diagnosis was 4 years, and median EDSS score at baseline was 2. The median time on study drug for all treatment arms was 96 weeks. The percentages of patients who completed 96 weeks on study drug per treatment group were 69% for patients assigned to dimethyl fumarate delayed-release capsules 240 mg twice a day, 69% for patients assigned to dimethyl fumarate delayed-release capsules 240 mg three times a day and 65% for patients assigned to placebo groups.

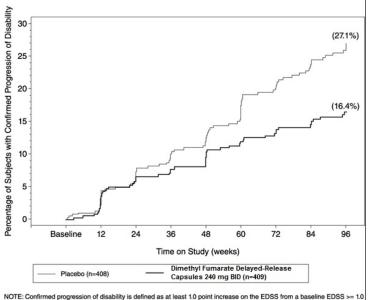
Dimethyl fumarate delayed-release capsules had a statistically significant effect on all of the endpoints described above and the 240 mg three times daily dose showed no additional benefit over the dimethyl fumarate delayed-release capsules 240 mg twice daily dose. The results for this study (240 mg twice a day vs. placebo) are shown in Table 2 and Figure 1.

	Dimethyl Fumarate Delayed-Release Capsules 2	240 mg BIDPlacebo	P-value
Clinical Endpoints	N=410	N=408	
Proportion relapsing (primary endpoint)	27%	46%	< 0.0001
Relative risk reduction	49%		
Annualized relapse rate	0.172	0.364	< 0.0001
Relative reduction	53%		
Proportion with disability progression	16%	27%	0.0050
Relative risk reduction	38%		
MRI Endpoints	N=152	N=165	
Mean number of new or newly enlarging T2 lesions over 2 years	2.6	17	< 0.0001
Percentage of subjects with no new or newly enlarging lesions	45%	27%	
Number of Gd+ lesions at 2 years Mean (median)	0.1 (0)	1.8 (0)	
Percentage of subjects with			
0 lesions	93%	62%	

Table 2: Clinical and MRI Results of Study 1

5%	10%
<1%	8%
0	9%
<1%	11%
90%	< 0.00
15	5.6 <0.00
	<1% 0 <1%

Elen	1. Time .	**	12 Week	Confirmed	Ducuuccelou		Disalation	(C1	. 1)
rigure	T: Lime	ιo	IZ-Week	Commed	Progression	UI	DISADIILY	(Study	<i>y</i> 1)



NOTE: Confirmed progression of disability is defined as at least 1.0 point increase on the EDSS from a baseline EDSS = 1.0 confirmed for 12 weeks or at least 1.5 point increase on the EDSS from a baseline EDSS of 0 confirmed for 12 weeks.

Study 2: Placebo-Controlled Trial in RRMS

Study 2 was a 2-year multicenter, randomized, double-blind, placebo-controlled study that also included an open-label comparator arm in patients with RRMS. The primary endpoint was the annualized relapse rate at 2 years. Additional endpoints at 2 years included the number of new or newly enlarging T2 hyperintense lesions, number of T1 hypointense lesions, number of Gd+ lesions, proportion of patients relapsed, and time to confirmed disability progression as defined in Study 1.

Patients were randomized to receive dimethyl fumarate delayed-release capsules 240 mg twice a day (n=359), dimethyl fumarate delayed-release capsules 240 mg three times a day (n=345), an open-label comparator (n=350), or placebo (n=363) for up to 2 years. The median age was 37 years, median time since diagnosis was 3 years, and median EDSS score at baseline was 2.5. The median time on study drug for all treatment arms was 96 weeks. The percentages of patients who completed 96 weeks on study drug per treatment group were 70% for patients assigned to dimethyl fumarate delayed-release capsules 240 mg twice a day, 72% for patients assigned to dimethyl fumarate delayed-release capsules 240 mg three times a day and 64% for patients assigned to placebo groups.

Dimethyl fumarate delayed-release capsules had a statistically significant effect on the relapse and MRI endpoints described above. There was no statistically significant effect on disability progression. The dimethyl fumarate delayed-release capsules 240 mg three times daily dose resulted in no additional benefit over the dimethyl fumarate delayed-release capsules 240 mg twice daily dose. The results for this study (240 mg twice a day vs. placebo) are shown in Table 3.

Table 3	: Clinical	and	MRI	Results	of	Study	2
---------	------------	-----	-----	---------	----	-------	---

	Dimethyl Fumarate Delayed-Release Capsules 240 mg BID	Placebo	P-value
Clinical Endpoints	N=359	N=363	
Annualized relapse rate	0.224	0.401	< 0.0001
Relative reduction	44%		
Proportion relapsing	29%	41%	0.0020
Relative risk reduction	34%		
Proportion with disability progression	13%	17%	0.25
Relative risk reduction	21%		
MRI Endpoints	N=147	N=144	
Mean number of new or newly enlarging T2 lesions over 2 years	s 5.1	17.4	< 0.0001

	270/	120/	
Percentage of subjects with no new or newly enlarging lesions	27%	12%	
Number of Gd+ lesions at 2 years			
Mean (median)	0.5 (0.0)	2.0 (0.0)	
Percentage of subjects with			
0 lesions	80%	61%	
1 lesion	11%	17%	
2 lesions	3%	6%	
3 to 4 lesions	3%	2%	
5 or more lesions	3%	14%	
Relative odds reduction (percentage)	74%		<0.0001
Mean number of new T1 hypointense lesions over 2 years	3.0	7.0	<0.0001

16 HOW SUPPLIED/STORAGE AND HANDLING

Dimethyl fumarate delayed-release capsules are available as hard gelatin delayed-release capsules in two strengths containing either 120 mg or 240 mg of dimethyl fumarate. The yellow cap and white body 120 mg capsules are imprinted with circular LU on cap and D76 on body in black ink. The yellow cap and body 240 mg capsules are imprinted with circular LU on cap and D77 on body in black ink. Dimethyl fumarate delayed-release capsules are available as follows:

30-day Starter Pack, (NDC 68180-778-13):

7-day bottle 120 mg capsules, quantity 14 (NDC 68180-776-65)

23-day bottle 240 mg capsules, quantity 46 (NDC 68180-777-48)

120 mg capsules:

7-day bottle of 14 capsules (NDC 68180-776-14)

240 mg capsules:

30-day bottle of 60 capsules (NDC 68180-777-07)

Store at 15° to 30°C (59° to 86°F). Protect the capsules from light. Store in original container.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information)

Dosage

Inform patients that they will be provided two strengths of dimethyl fumarate delayedrelease capsules when starting treatment: 120 mg capsules for the 7 day starter dose and 240 mg capsules for the maintenance dose, both to be taken twice daily. Inform patients to swallow dimethyl fumarate delayed-release capsules whole and intact. Inform patients to not crush, chew, or sprinkle capsule contents on food. Inform patients that dimethyl fumarate delayed-release capsules can be taken with or without food [see DOSAGE AND ADMINISTRATION (2.1)].

Anaphylaxis and Angioedema

Advise patients to discontinue dimethyl fumarate and seek medical care if they develop signs and symptoms of anaphylaxis or angioedema [see WARNINGS AND PRECAUTIONS (5.1)].

Progressive Multifocal Leukoencephalopathy

Inform patients that progressive multifocal leukoencephalopathy (PML) has occurred in patients who received dimethyl fumarate. Inform the patient that PML is characterized by a progression of deficits and usually leads to death or severe disability over weeks or months. Instruct the patient of the importance of contacting their doctor if they develop any symptoms suggestive of PML. Inform the patient that typical symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes [see WARNINGS AND PRECAUTIONS (5.2)].

Herpes Zoster and Other Serious Opportunistic Infections

Inform patients that herpes zoster and other serious opportunistic infections have occurred in patients who received dimethyl fumarate. Instruct the patient of the importance of contacting their doctor if they develop any signs or symptoms associated with herpes zoster or other serious opportunistic infections [see WARNINGS AND PRECAUTIONS (5.3)].

Lymphocyte Counts

Inform patients that dimethyl fumarate may decrease lymphocyte counts. A blood test should be obtained before they start therapy. Blood tests are also recommended after 6 months of treatment, every 6 to 12 months thereafter, and as clinically indicated [see WARNINGS AND PRECAUTIONS (5.4), ADVERSE REACTIONS (6.1)].

Liver Injury

Inform patients that dimethyl fumarate may cause liver injury. Instruct patients treated with dimethyl fumarate to report promptly any symptoms that may indicate liver injury, including fatigue, anorexia, right upper abdominal discomfort, dark urine, or jaundice. A blood test should be obtained before patients start therapy and during treatment, as clinically indicated [see WARNINGS AND PRECAUTIONS (5.5)].

Flushing and Gastrointestinal (GI) Reactions

Flushing and GI reactions (abdominal pain, diarrhea, and nausea) are the most common reactions, especially at the initiation of therapy, and may decrease over time. Advise patients to contact their healthcare provider if they experience persistent and/or severe flushing or GI reactions. Advise patients experiencing flushing that taking dimethyl fumarate with food or taking a non-enteric coated aspirin prior to taking dimethyl fumarate may help [see ADVERSE REACTIONS (6.1)].

Pregnancy

Instruct patients that if they are pregnant or plan to become pregnant while taking dimethyl fumarate they should inform their physician.

Manufactured for:

Lupin Pharmaceuticals, Inc.

Baltimore, Maryland 21202

United States

Manufactured by:

Aizant Drug Research Solutions Private Limited,

Hyderabad, Telangana - 500 100,

INDIA

April 2021 XXXXXXXX ID#:

Patient Information

DIMETHYL FUMARATE Delayed-Release Capsules

(dye-meth-il FYOO-ma-rate)

What is Dimethyl Fumarate Delayed-Release Capsules?

- Dimethyl fumarate delayed-release capsules are a prescription medicine used to treat relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
- It is not known if dimethyl fumarate delayed-release capsules is safe and effective in children under 18 years of age

Who should not take Dimethyl Fumarate Delayed-Release Capsules?

 Do not use dimethyl fumarate delayed-release capsules if you have had an allergic reaction (such as welts, hives, swelling of the face, lips, mouth or tongue, or difficulty breathing) to dimethyl fumarate delayed-release capsules or any of its ingredients. See below for a complete list of ingredients.

Before taking and while you take Dimethyl Fumarate Delayed-Release Capsules, tell your doctor if you have or have had:

- low white blood cell counts or an infection
- any other medical conditions

Tell your doctor if you are:

- pregnant or plan to become pregnant. It is not known if dimethyl fumarate delayedrelease capsules will harm your unborn baby.
- breastfeeding or plan to breastfeed. It is not known if dimethyl fumarate passes into your breast milk. You and your doctor should decide if you will take dimethyl
- fumarate delayed-release capsules or breastfeed.taking prescription or over-the-counter medicines, vitamins, or herbal supplements

How should I take Dimethyl Fumarate Delayed-Release Capsules?

- Take dimethyl fumarate delayed-release capsules exactly as your doctor tells you to take it
- The recommended starting dose is one 120 mg capsule taken by mouth 2 times a day for 7 days
- The recommended dose after 7 days is one 240 mg capsule taken by mouth 2 times a day
- Dimethyl fumarate delayed-release capsules can be taken with or without food
- Swallow dimethyl fumarate delayed-release capsules whole. Do not crush, chew, or sprinkle capsule contents on food.
- Protect dimethyl fumarate delayed-release capsules from light. You can do this by storing the capsules in their original container.
- If you take too much dimethyl fumarate delayed-release capsules, call your doctor or go to the nearest hospital emergency room right away.

What are the possible side effects of Dimethyl Fumarate Delayed-Release Capsules?

Dimethyl fumarate delayed-release capsules may cause serious side effects including:

- allergic reaction (such as welts, hives, swelling of the face, lips, mouth or tongue, or difficulty breathing)
- PML a rare brain infection that usually leads to death or severe disability
- decreases in your white blood cell count Your doctor should do a blood test before you start treatment with dimethyl fumarate delayed-release capsules and while on therapy.
- **liver problems.** Your doctor should do blood tests to check your liver function before you start taking dimethyl fumarate delayed-release capsules and during treatment if needed. Tell your doctor right away if you get any of these symptoms of a liver problem during treatment.
 - severe tiredness
 - loss of appetite
 - pain on the right side of your stomach
 - have dark or brown (tea color) urine
 - yellowing of your skin or the white part of your eyes
- herpes zoster infections (shingles), including central nervous system infections
- other serious infections

The most common side effects of Dimethyl Fumarate Delayed-Release Capsules include:

- flushing, redness, itching, or rash
- nausea, vomiting, diarrhea, stomach pain, or indigestion
- Flushing and stomach problems are the most common reactions, especially at the start of therapy, and may decrease over time. Taking dimethyl fumarate delayedrelease capsules with food may help reduce flushing. Call your doctor if you have any of these symptoms and they bother you or do not go away. Ask your doctor if taking aspirin before taking dimethyl fumarate delayed-release capsules may reduce flushing.

These are not all the possible side effects of dimethyl fumarate delayed-release capsules. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov.**

For more information go to www.lupinpharmaceuticals.com or call 1-800-399-2561.

General Information about the safe and effective use of Dimethyl Fumarate Delayed-Release Capsules

- Medicines are sometimes prescribed for purposes other than those listed in this
 Patient Information. Do not use dimethyl fumarate delayed-release capsules for a
 condition for which it was not prescribed. Do not give dimethyl fumarate delayedrelease capsules to other people, even if they have the same symptoms that you
 have. It may harm them.
- If you would like more information, talk to your doctor or pharmacist. You can ask your doctor or pharmacist for information about dimethyl fumarate delayed-release capsules that is written for healthcare professionals.

What are the ingredients in Dimethyl Fumarate Delayed-Release Capsules?

Active ingredient: dimethyl fumarate

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, methacrylic acid copolymer - Type A, methacrylic acid copolymer dispersion, silicified microcrystalline cellulose, talc and triethyl citrate. **Capsule Shell:** black iron oxide, D & C yellow 10, FD & C yellow 6, gelatin, potassium hydroxide, propylene glycol, shellac, strong ammonia solution and titanium dioxide.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Manufactured for:

Lupin Pharmaceuticals, Inc.

Baltimore, Maryland 21202

United States

Manufactured by:

Aizant Drug Research Solutions Private Limited,

Hyderabad, Telangana - 500 100, INDIA April 2021 ID#:XXXXXXX

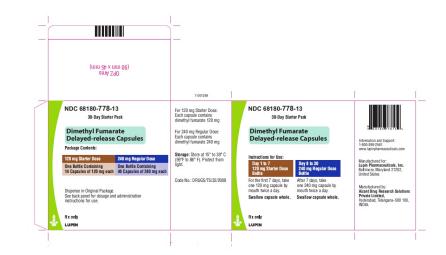
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Starter Pack: Carton Label: NDC 68180-778-13 30-Day Starter Pack Dimethyl Fumarate Delayed-Release Capsules Package Contents: NDC 68180-776-65: 120 mg Starter Dose One bottle containing 14 capsules of 120 mg each NDC 68180-777-48: 240 mg Regular Dose

One bottle containing 46 capsules of 240 mg each

Dispense in Original Package.

See back panel for dosage and administration instructions for use.







NDC 68180-776-14

Dimethyl Fumarate Delayed-Release Capsules 120 mg

7-day bottle of 14 capsules



	_		
68лА Z9O (mm S4 x mm S4)			
	11001271		
NDC 68180-776-14	Henel Decene Take one	NDC 68180-776-14	
Dimethyl Fumarate Delayed-release Capsules	Usual Dosage: Take one capsule by mouth twice a day. See accompanying prescribing information.	Dimethyl Fumarate Delayed-release Capsules	N 1681801776141117
120 mg Dispense in Original Package. Swallow capsule whole.	Storage: Store at 15° to 30° C (59°F to 86° F). Protect from light.	120 mg Dispense in Original Package. Swallow capsule whole.	Information and Support: 1-800-399-2561 www.lupinpharmaceuticals.com
Each capsule contains dimethyl fumarate 120 mg		Each capsule contains dimethyl fumarate 120 mg	Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, United States
Rx only	Code No.: DRUGS/TS/32/2008	Rx only LUPIN 14 Capsules	Manufactured by: Aizant Drug Research Solutions Private Limited, Hyderabad, Telangana–500 100, INDIA.

NDC 68180-777-07

Dimethyl Fumarate Delayed-Release Capsules

240 mg

30-day bottle of 60 capsules

NDC 68180-777-07	Each capsule contains dimethyl fumarate 240 mg	
Dimethyl Fumarate Delayed-release Capsules	Usual Dosage: Take one capsule by mouth twice a day. See accompanying prescribing information.	Unvarnish Area 45 x 20 mm
240 mg	Storage: Store at 15° to 30° C (59°F to 86° F). Protect from light. Store in original container.	22 22
Swallow capsule whole.	Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, United States	3 6 8 1 8 0 17 7 7 0 7 6 0 0 0 0 0 0 0 0 0 0 0 0 0 0
Rx only 60 Capsules	Manufactured by: Aizant Drug Research Solutions Private Limited, Hyderabad, Telangana – 500 100, INDIA.	

s91A Z90 (mm S8 x mm S8)				
	11001270			
NDC 68180-777-07	Usual Dosage: Take one capsule by mouth twice a day. See accompanying	NDC 68180-777-07	31	
Dimethyl Fumarate Delayed-release Capsules	prescribing information. Storage: Store at 15° to 30° C	Dimethyl Fumarate Delayed-release Capsules		
240 mg Dispense in Original Package. Swallow capsule whole.	(59°F to 86° F). Protect from light.	240 mg Dispense in Original Package. Swallow capsule whole.	Information and Support: 1-800-399-2561 www.lupinpharmaceuticals.com Manufactured for: Lupin Pharmaceuticals.Inc.	
Each capsule contains dimethyl fumarate 240 mg		Each capsule contains dimethyl fumarate 240 mg	Baltimore, Maryland 21202, United States	
Rx only LUPIN 60 Capsules	Code No.: DRUGS/TS/32/2008	Rx only	Manufactured by: Aizant Drug Research Solutions Private Limited, Hyderabad, Telangana-500 100, INDIA.	

Product Infor							
	mation						
Product Type	HUMAN PR	ESCRIPTION DRUG	ľ	tem Code (Sour	e)	NDC:6818	80-778
Packaging							
# Item Code		kage Description		Marketing S Date	itart	Marketi Da	
1 NDC:68180-778- 13	1 in 1 KIT; Ty Product	vpe 0: Not a Combinatio	n	10/31/2020			
Quantity of Pa	arte						
Part #		Juantity		Total Br	aduct O	uantitu	
Part # Part 1 1 BOTTLE	Package (quantity	14	Total Pro	Jauct Q	uantity	
Part 2 1 BOTTLE			14 46				
unneurynunnarai		alavad ralaaca					
Product Infor Route of Admini Active Ingredi	mation stration	oraL Moiety					
Route of Admini	mation stration ent/Active	ORAL				sis of ength	Strength
Route of Admini Active Ingredi DIMETHYL FUMAR	mation stration ent/Active Ing	oral Moiety	L FUMA	RATE -	Str		
Route of Admini Active Ingredi	mation stration ent/Active Ing ATE (UNII: FO2	ORAL Moiety predient Name	L FUMA	RATE -	Str	ength	
Route of Admini Active Ingredi DIMETHYL FUMAR UNII:45IUB1PX8R) Inactive Ingre	mation stration ent/Active Ing ATE (UNII: FO2 dients	ORAL Moiety predient Name		RATE -	Str	ength L FUMARATE	
Route of Admini Active Ingredi DIMETHYL FUMAR UNII:45IUB1PX8R) Inactive Ingre AMMONIA (UNII: 51	mation stration ent/Active Ing ATE (UNII: FO2 dients 38Q19F1X)	ORAL Moiety predient Name 303MNI2) (MONOMETHY Ingredient Na		RATE -	Str	ength L FUMARATE	120 mg
Route of Admini Active Ingredi DIMETHYL FUMAR UNII:45IUB1PX8R) Inactive Ingre AMMONIA (UNII: 51 CELLULOSE, MICR	mation stration ent/Active Ing ATE (UNII: FO2 dients 38Q19F1X) OCRYSTALLIN	ORAL Moiety predient Name 303MNI2) (MONOMETHY Ingredient N: III (UNII: OP1R32D61U)		RATE -	Str	ength L FUMARATE	120 mg
Route of Admini Active Ingredi DIMETHYL FUMAR UNII:45IUB1PX8R) Inactive Ingre AMMONIA (UNII: 51 CELLULOSE, MICR CROSCARMELLOSI	mation stration ent/Active Ing ATE (UNII: FO2 dients 380(19F1X) OCRYSTALLIN E SODIUM (UN	ORAL Moiety predient Name 303MNI2) (MONOMETHY Ingredient N: III (UNII: OP1R32D61U) III: M280L1HH48)		RATE -	Str	ength L FUMARATE	120 mg
Route of Admini Active Ingredi DIMETHYL FUMAR UNII:45IUB1PX8R) Inactive Ingre AMMONIA (UNII: 51 CELLULOSE, MICR CROSCARMELLOSI D&C YELLOW NO.	mation stration ent/Active ing ATE (UNII: FO2 dients 38Q19F1X) OCRYSTALLIN E SODIUM (UN 10 (UNII: 355V	ORAL Moiety predient Name 303MNI2) (MONOMETHY Ingredient N. IE (UNII: OP1R32D61U) III: M280L1HH48) M5USQ3G)		RATE -	Str	ength L FUMARATE	120 mg
Route of Admini Active Ingredi DIMETHYL FUMAR UNII:45IUB1PX8R) Inactive Ingre AMMONIA (UNII: 51 CELLULOSE, MICR CROSCARMELLOSI D&C YELLOW NO. FD&C YELLOW NO	mation stration ent/Active ing ATE (UNII: FO2 dients 380(19F1X) OCRYSTALLIN E SODIUM (UN 10 (UNII: 355V 0. 6 (UNII: H7TV	ORAL Moiety predient Name 303MNI2) (MONOMETHY Ingredient N: IE (UNII: OP1R32D61U) III: M280L1HH48) W5USQ3G) /EI93A8)		RATE -	Str	ength L FUMARATE	120 mg
Route of Admini Active Ingredi DIMETHYL FUMAR UNII:45IUB1PX8R) Inactive Ingre AMMONIA (UNII: 51	mation stration ent/Active ing ATE (UNII: FO2 dients 380(19F1X) OCRYSTALLIN E SODIUM (UN 10 (UNII: 355V 0. 6 (UNII: H77V DXIDE (UNII: X7	ORAL Moiety predient Name 303MNI2) (MONOMETHY Ingredient N: IE (UNII: OP1R32D61U) III: M280L1HH48) W5USQ3G) /EI93A8)		RATE -	Str	ength L FUMARATE	120 mg

-										
			(UNII: 6DC9Q167V3)						
	LLAC (UNII:									
			III: ETJ7Z6XBU4)							
	C (UNII: 75E									
			JNII: 15FIX9V2JP)							
TRIE	ETHYL CITE	RATE (l	JNII: 8Z96QXD6UM)							
-										
Pro	oduct Ch									
Col	or	Y	ELLOW (Cap),WHITE	E (Body)		Score		no	score	
Sha	pe	C	APSULE			Size		19	mm	
Flay	vor					Imprint C	ode	LU	;D76	
Con	itains									
Pa	ckaging									
#	Item		Package De	escription	Ma	arketing S	Start	Marke	ting E	nd
-	Code		Tackage Da	escription		Date		D	ate	
1			1 BOTTLE; Type 0: N	Not a Combination						
		Produ	ct							
Ma	arketin	g In	formation							
	Marketin	g	Application N	umber or Mono	graph	Marketii	ng Start	Mark	eting	End
	Category	ÿ		Citation		Da	te		Date	
AND	A		ANDA210226			10/31/2020				
Pa	rt 2 of	2								
Fa		-								
DI	ΜΕΤΗΥ	L FU	JMARATE							
dim	nethyl fum	arate	capsule, delayed	d release						
	· · ·									
Pro	oduct In	form	ation							
Rou	ute of Adn	ninist	ration ORAL							
Act	tive Inar	odior	ot/Active Moiet	hv						
Act	tive Ingr	edier	nt/Active Moiel	ty						
Act	tive Ingr	edier	nt/Active Moiet	-				is of	Stre	engt
	-		Ingredie	nt Name	UMARATE -		Stre	ngth		-
DIM	-	MARAT		nt Name	UMARATE -			ngth		-
DIM	ETHYL FUN	MARAT	Ingredie	nt Name	UMARATE -		Stre	ngth		-
DIM	ETHYL FUN	MARAT	Ingredie	nt Name	UMARATE -		Stre	ngth		-
DIM UNII:	ETHYL FUN	MARAT R)	Ingredien E (UNII: FO2303MNIZ	nt Name	UMARATE -		Stre	ngth		-
DIM UNII:	ETHYL FUN 45IUB1PX8F	MARAT R)	Ingredier E (UNII: FO2303MNIZ ents	nt Name			Stre	ngth	240	mg
DIM UNII:	ETHYL FUN 45IUB1PX8F	marat ^{R)} gredi	Ingredier E (UNII: FO2303MNI2 ents	nt Name 2) (MONOMETHYL FI			Stre	ngth	240	mg
	ETHYL FUN 45IUB1PX8 Active Ing MONIA (UNI	MARAT R) gredi	Ingredie E (UNII: F02303MNI ents I Q19F1X)	nt Name 2) (MONOMETHYL FI ngredient Nam			Stre	ngth	240	mg
	ETHYL FUN 45IUB1PX8f Active Ing MONIA (UNII LULOSE, M	MARAT R) gredi I: 5138 IICROC	Ingredier E (UNII: FO2303MNI2 ents	nt Name 2) (MONOMETHYL FI ngredient Nam : OP1R32D61U)			Stre	ngth	240	mg
	ETHYL FUN 45IUB1PX8f Active Ing MONIA (UNII LULOSE, M DSCARMELL	gredi si: 5138 sic Roc Lose s	Ingredier E (UNII: FO2303MNI2 ents I Q19F1X) :RYSTALLINE (UNII:	nt Name 2) (MONOMETHYL FI ngredient Nam 2 OP1R32D61U) DL1HH48)			Stre	ngth	240	mg
DIM UNII Ina AMN CEL CRC D&C	ETHYL FUN 45IUB1PX8f MONIA (UNII LULOSE, M DSCARMELL 2 YELLOW	gredi si 51384 lic ROC LOSE S NO. 10	Ingredier E (UNII: FO2303MNI2 ents I Q19F1X) CRYSTALLINE (UNII: SODIUM (UNII: M280	nt Name 2) (MONOMETHYL FU ngredient Nam 6 OP1R32D61U) DL1HH48) G)			Stre	ngth	240	mg
DIM UNII: AMM CEL CRO D&C FD&	ETHYL FUN 45IUB1PX8F MONIA (UNII LULOSE, M DSCARMELL 2 YELLOW 4C YELLOW	gredi I: 51384 IICROC LOSE S NO. 10 / NO. 6	Ingredier E (UNII: F02303MNI2 ents (21951X) RYSTALLINE (UNII: CODIUM (UNII: M28C O (UNII: 355V5U5Q3	nt Name 2) (MONOMETHYL FU ngredient Nam (OP1R32D61U) DL1HH48) G)			Stre	ngth	240	engtl mg ngth
DIM UNII: AMM CEL CRO D&C FD& FER	ETHYL FUN 45IUB1PX8F MONIA (UNII LULOSE, M DSCARMELL 2 YELLOW 4C YELLOW	MARAT R) I: 5138 IICROC LOSE S NO. 10 / NO. 6 RIC OX	Ingredier E (UNII: F02303MNI2 ents U1951X) CRYSTALLINE (UNII: 500TUM (UNII: M28C 500TUM (UNII: 355W5USQ3 5 (UNII: H77VE193A8) IDE (UNII: XM0M87F3	nt Name 2) (MONOMETHYL FU ngredient Nam (OP1R32D61U) DL1HH48) G)			Stre	ngth	240	mg
DIM UNII: AMM CEL CRC D&C FD& FER GEL	ETHYL FUN 445IUB1PX8/ MONIA (UNII LULOSE, M DSCARMELI CYELLOW C YELLOW ROSOFERR ATIN (UNII:	MARAT R) gredi I: 51384 IICROC LOSE S NO. 10 / NO. 6 RIC OXI 2G86Q	Ingredier E (UNII: F02303MNI2 ents U1951X) CRYSTALLINE (UNII: 500TUM (UNII: M28C 500TUM (UNII: 355W5USQ3 5 (UNII: H77VE193A8) IDE (UNII: XM0M87F3	nt Name 2) (MONOMETHYL FI ngredient Nam : OP1R32D61U) DL1HH48) G)) 3557)			Stre	ngth	240	mg
DIM UNII: AMM CEL CRO D&C FD& FER GEL MAC	ETHYL FUN 445IUB1PX8/ MONIA (UNII LULOSE, M SCARMELL 2 YELLOW 4C YELLOW 4C YELLOW 5C YELLOW 5C STATIN (UNII: 5NESIUM S'	gredi I: 5138 IICROC LOSE S NO. 10 / NO. 6 RIC OXI 2G86Q TEARA	Ingredier E (UNII: F02303MNI2 ents U19F1X) RYSTALLINE (UNII: SODIUM (UNII: M28C) O (UNII: 355V5USQ3 6 (UNII: H7VE193A8) IDE (UNII: XMOM87F; IN327L)	nt Name 2) (MONOMETHYL FI ngredient Nam : OP1R32D61U) DL1HH48) G)) 3557) 30)	e	(UNII: NX76	Stre	ngth	240	mg
DIM UNII: AMN CEL CRC D&C FD& FER GEL MAC MET	ETHYL FUN 445IUB1PX8/ MONIA (UNII LULOSE, M SCARMELL 2 YELLOW 4C YELLOW 4C YELLOW TROSOFERR ATIN (UNII: SNESIUM S' FHACRYLIC	gredi I: 5138 IICROC LOSE S NO. 10 / NO. 6 RIC OXI 2G86Q TEARA ACID	Ingredier E (UNII: F02303MNI2 ents U219F1X) :RYSTALLINE (UNII: SODIUM (UNII: M28C 0 (UNII: 355W5U5Q3 0 (UNII: 177VE193A8) IDE (UNII: XM0M87F: IN327L) TE (UNII: 70097M612	nt Name 2) (MONOMETHYL FI ngredient Nam : OP1R32D61U))L1HH48) G)) 357) 30) E COPOLYMER (1:	1) TYPE A		Stre DIMETHYL	ngth	240	mg
DIM UNII: AMM CEL CRO D&C FD& FER GEL MAC MET MET	ETHYL FUN 445IUB1PX8/ MONIA (UNII LULOSE, M SCARMELL 2 YELLOW 4C YELLOW ROSOFERF ATIN (UNII: SNESIUM 52 FHACRYLIC THACRYLIC	gredi I: 51384 IICROC LOSE S NO. 10 / NO. 6 RIC OX 2G86Q TEARA ACID - ACID -	Ingredier E (UNII: F02303MNI2 ents U219F1X) :RYSTALLINE (UNII: SODIUM (UNII: M28C 0 (UNII: 177VE193A8) 10E (UNII: XM0M87F: N327L) TE (UNII: 70097M612 - ETHYL ACRYLATE	nt Name 2) (MONOMETHYL FI ngredient Nam 3) OP1R32D61U) 2)L1HH48) G) 3) 357) 30) E COPOLYMER (1: CRYLATE COPOLY	1) TYPE A		Stre DIMETHYL	ngth	240	mg
DIM UNII: AMN CEL CRO D&C FD& FER GEL MAC MET POT	ETHYL FUN 44510B1PX8/ MONIA (UNII LULOSE, M SCARMELL 2 YELLOW ROSOFERA ATIN (UNII: SINESIUM S' THACRYLIC TACRYLIC CASSIUM HY	MARAT R) gredi II: 5138 III: ROC LOSE S NO. 10 II: COC II: COC	Ingredie: E (UNII: F02303MNI2 ents U219F1X) CRYSTALLINE (UNII: SODIUM (UNII: M28C 0 (UNII: 555W5USQ3 5 (UNII: 555W5USQ3 5 (UNII: 77VE193A8) IDE (UNII: 77VE193A8) IDE (UNII: 70097M612 • ETHYL ACRYLATE • METHYL METHAC	nt Name 2) (MONOMETHYL FI ngredient Nam c OP1R32D61U) DL1HH48) G) 357) 30) E COPOLYMER (1: CRYLATE COPOLY BM4T)	1) TYPE A		Stre DIMETHYL	ngth	240	mg
DIM UNII AMN CEL CRO D&C FD& FER GEL MAC MET POT PRO	ETHYL FUN 44510B1PX8/ MONIA (UNII LULOSE, M SCARMELL 2 YELLOW ROSOFERA ATIN (UNII: SINESIUM S' THACRYLIC TACRYLIC CASSIUM HY	MARAT R) I: 51388 IIICROC LOSE S NO. 100 I NO. 6 RIC OXI 2086Q TEARA ACID ACID YDROX LYCOL	Ingredier E (UNII: F02303MNI2 ents (UNII: F02303MNI2 ents (UNII: F02303MNI2 (UNII: 352W5U503 (UNII: 472VE193A8) IDE (UNII: 355W5U503 (UNII: 472VE193A8) IDE (UNII: 4	nt Name 2) (MONOMETHYL FI ngredient Nam c OP1R32D61U) DL1HH48) G) 357) 30) E COPOLYMER (1: CRYLATE COPOLY BM4T)	1) TYPE A		Stre DIMETHYL	ngth	240	mg
DIM UNII AMN CEL CRO D&C FD& FER GEL MAC MET POT PRO SHE	ETHYL FUN 445IUB1PX8/ 445IUB1PX8/ 445IUB1PX8/ 400NIA (UNII ULUCSE, M 95CARMELI C YELLOW ROSOFERA ATIN (UNII: SNESIUM S' FHACRYLIC FHACRYLIC FASSIUM H PPYLENE GI ULLAC (UNII:	MARAT R) I: 51388 IIICROC LOSE S NO. 10 VI NO. 6 RIC OXI 2G86Q TEARA ACID ACID 4CID YDROX LYCOL 46N10	Ingredier E (UNII: F02303MNI2 ents (UNII: F02303MNI2 ents (UNII: F02303MNI2 (UNII: 352W5U503 (UNII: 472VE193A8) IDE (UNII: 355W5U503 (UNII: 472VE193A8) IDE (UNII: 4	nt Name 2) (MONOMETHYL FI ngredient Nam c OP1R32D61U) DL1HH48) G) 357) 30) E COPOLYMER (1: CRYLATE COPOLY BM4T)	1) TYPE A		Stre DIMETHYL	ngth	240	mg
DIM UNII: AMM CEL CRO D&C FD& FER GEL MAC MET POT PRO SHE SILI	ETHYL FUN 445IUB1PX8/ 445IUB1PX8/ 445IUB1PX8/ 400NIA (UNII ULUCSE, M 95CARMELI C YELLOW ROSOFERA ATIN (UNII: SNESIUM S' FHACRYLIC FHACRYLIC FASSIUM H PPYLENE GI ULLAC (UNII:	MARAT R) gredi I: 5138 IICROO LOSE S NO. 10 / NO. 6 KIC OXIX 2G860 ACID YDROX LYCOL 46N10 DE (UN	Ingredier E (UNII: FO2303MNI2 ents U19F1X) RYSTALLINE (UNII: SODIUM (UNII: M28K O (UNII: 355V5U5Q3 5 (UNII: H77VE193A8) DIDE (UNII: XM0M87F: IN327L) TE (UNII: 70097M6I: FTHYL ACRYLATE METHYL MCTHAC48 (UNII: 6DC9Q167V3 IDE (UNII: WZH3C48 (UNII: 6DC9Q167V3 IDE (UNII: 6DC9Q167V3 IDE (UNII) (IDE (UNII	nt Name 2) (MONOMETHYL FI ngredient Nam c OP1R32D61U) DL1HH48) G) 357) 30) E COPOLYMER (1: CRYLATE COPOLY BM4T)	1) TYPE A		Stre DIMETHYL	ngth	240	mg
DIM UNII: AMN CEL CRO D&C FD& FER GEL MAC MET POT PRO SHE SILI TAL	ETHYL FUN 445IUB1PX8/ 40NIA (UNII LULOSE, M ISCARMELL CYELLOW ROSOFERR ATIN (UNII: SINESIUM S' FHACRYLIC THACRYLIC THACRYLIC CASSIUM HY POPLENE GI LLLAC (UNII: CON DIOXI C (UNII: 75E	MARAT R) gredi I: 51384 IICROC JOSE 5 NO. 10 2086Q TEARA ACID - VORX ZGB6Q TEARA ACID - ACID - VICOL 46N10 LYCOL 46N10 DE (UM	Ingredier E (UNII: FO2303MNI2 ents U19F1X) RYSTALLINE (UNII: SODIUM (UNII: M28K) O (UNII: 355V5U5Q3 5 (UNII: H77VE193A8) DIDE (UNII: XM0M87F: IN327L) TE (UNII: 70097M6I: - ETHYL ACRYLATE - METHYL - METHYL ACRYLATE - METHYL - METHYL - METHYL - METHYL - METHYL - MET	nt Name 2) (MONOMETHYL FI ngredient Nam c OP1R32D61U) DL1HH48) G) 357) 30) E COPOLYMER (1: CRYLATE COPOLY BM4T)	1) TYPE A		Stre DIMETHYL	ngth	240	mg
DIM UNII: AMM CEL CRO D&C FD& FER GEL MAC MET POT PRO SHE SILI TAL TITZ	ETHYL FUN 44510B1PX8/ 400NIA (UNII LULOSE, M SCARMELL 2 YELLOW 4C YELLOW 4C YELLOW 4C YELLOW 4C YELLOW 14C RSOFERR ATIN (UNII: SINESIUM S' FHACRYLIC 4ASSIUM HY PYLENE GI LLLAC (UNII: C ON DIOXI C (UNII: 75E ANIUM DIOX	MARAT R) gredi II: 51384 II: CROC LOSE S NO. 10 / NO. 6 ZG86Q TEARA ACID - XCID	Ingredier E (UNII: FO2303MNI2 ents Q19F1X) :RYSTALLINE (UNII: :RYSTALLINE (UNII: :RYSTALLINE (UNII: :SODIUM (UNII: M206 0 (UNII: H77VE193A8) IDE (UNII: T77VE193A8) IDE (UNII: T77VE193A8) IDE (UNII: T77VE193A8) IDE (UNII: T77VE193A8) - ETHYL ACRYLATE - METHYL ACRYLATE - METHYL ACRYLATE (UNII: 6DC9Q167V3 78710) III: ETJ7Z6XBU4) U)	nt Name 2) (MONOMETHYL FI ngredient Nam c OP1R32D61U) DL1HH48) G) 357) 30) E COPOLYMER (1: CRYLATE COPOLY BM4T)	1) TYPE A		Stre DIMETHYL	ngth	240	mg
DIM UNII: AMM CEL CRO D&C FD& FER GEL MAC MET POT PRO SHE SILI TAL TITA	ETHYL FUN 44510B1PX8/ 400NIA (UNII LULOSE, M SCARMELL 2 YELLOW 4C YELLOW 4C YELLOW 4C YELLOW 4C YELLOW 14C RSOFERR ATIN (UNII: SINESIUM S' FHACRYLIC 4ASSIUM HY PYLENE GI LLLAC (UNII: C ON DIOXI C (UNII: 75E ANIUM DIOX	MARAT R) gredi II: 51384 II: CROC LOSE S NO. 10 / NO. 6 ZG86Q TEARA ACID - XCID	Ingredier E (UNII: FO2303MNI ents Q19F1X) :RYSTALLINE (UNII: SODIUM (UNII: M28G 0 (UNII: 355W5U5Q3 5 (UNII: H77VE193A8) 10E (UNII: 355W5U5Q3 5 (UNII: M77VE193A8) 10E (UNII: GDC9Q167V3 178710) UNII: ETJ726XBU4) U)	nt Name 2) (MONOMETHYL FI ngredient Nam c OP1R32D61U) DL1HH48) G) 357) 30) E COPOLYMER (1: CRYLATE COPOLY BM4T)	1) TYPE A		Stre DIMETHYL	ngth	240	mg
DIM UNII: AMM CEL CRO D&C FD& FER GEL MAC MET POT PRO SHE SILI TAL TITA	ETHYL FUN 44510B1PX8/ 400NIA (UNII LULOSE, M SCARMELL 2 YELLOW 4C YELLOW 4C YELLOW 4C YELLOW 4C YELLOW 14C RSOFERR ATIN (UNII: SINESIUM S' FHACRYLIC 4ASSIUM HY PYLENE GI LLLAC (UNII: C ON DIOXI C (UNII: 75E ANIUM DIOX	MARAT R) gredi II: 51384 II: CROC LOSE S NO. 10 / NO. 6 ZG86Q TEARA ACID - XCID	Ingredier E (UNII: FO2303MNI ents Q19F1X) :RYSTALLINE (UNII: SODIUM (UNII: M28G 0 (UNII: 355W5U5Q3 5 (UNII: H77VE193A8) 10E (UNII: 355W5U5Q3 5 (UNII: M77VE193A8) 10E (UNII: GDC9Q167V3 178710) UNII: ETJ726XBU4) U)	nt Name 2) (MONOMETHYL FI ngredient Nam c OP1R32D61U) DL1HH48) G) 357) 30) E COPOLYMER (1: CRYLATE COPOLY BM4T)	1) TYPE A		Stre DIMETHYL	ngth	240	mg
DIM UNII AMN CEL CRO D&C FD& FER GEL MAC MET POT PRO SHE SILI TAL TIT/ TRIE	ETHYL FUN 4510B1PX8/ 4510B1PX8/ 4510B1PX8/ 400NIA (UNII ULUOSE, M SOSCARMELL 5 YELLOW ROSOFERR ATIN (UNII: 5 NESIUM S' FHACRYLIC FHACRYLIC FHACRYLIC FHACRYLIC FHACRYLIC CON DIOXI CON DIOXI C (UNII: 75E ANIUM DIO: 5 THYL CITF	MARAT R) gredi I: 5138 HICROC LOSE S NO. 1(C V NO. 6 V NO. 1 V VO VO V V V V V V V V V V V V V V V	Ingredier E (UNII: F02303MNI2 ents Q19F1X) RYSTALLINE (UNII: M28C 50UUM (UNII: 35W5U5Q3 50UUM (UNII: 35W5U5Q3 50UUM (UNII: 35W5U5Q3 50UUM (UNII: 70097MGI3 50UUMI: H77VE193A8) IDE (UNII: 70097MGI3 50UUMI: 70097MG	nt Name 2) (MONOMETHYL FI ngredient Nam c OP1R32D61U) DL1HH48) G) 357) 30) E COPOLYMER (1: CRYLATE COPOLY BM4T)	1) TYPE A		Stre DIMETHYL	ngth	240	mg
DIM UNII AMN CEL CRO D&C F D& F ER MAC MET POT PRO SHE SILI TAL TAL TAL	ETHYL FUN 451UB1PX81 451UB1PX81 40NIA (UNII LULOSE, M DSSCARMELL 5 YELLOW IC YELLOW ROSOFERR ATIN (UNII: 5 NESIUM 5' FHACRYLIC FHACRYLIC FHACRYLIC FACRYLIC CON DIOXI CON DIOXI CON DIOXI C (UNII: 75E ANIUM DIO: 5 THYL CITF	MARAT R) gredi I: 5138 IICROC LOSE S VICOL ZG86Q TEARA ACID ZG86Q TEARA ACID YDROX YDROX VYOROL LYCOL 46N10 DE (UN XIDE (U XIDE (U XID	Ingredier E (UNII: F02303MNI2 ents (21951x) CRYSTALLINE (UNII: M280C 5001UM (UNII: M280C 5001UM (UNII: M280C 5001UM (UNII: M280C 5001UM (UNII: M280C 501UM (UNII: M280C 501UM (UNII: M280C 501UM (UNII: M280C 1000 (UNII: M280C 1000 (UNII: M280C 1000 (UNII: M280C 1000 (UNII: M280C 1000 (UNII: M280C 1000 (UNII: S000C 1000 (UNII: S000C 1000 (UNII: S15100C) 1000 (UNII: S296QXD6UM) 1000 (UNII: S296QXD6UM)	nt Name 2) (MONOMETHYL FI ngredient Nam 2) (MONOMETHYL FI ngredient Nam 2) (DP1R32D61U) 2) (DP1R32D61U) 2) (DP1R32D61U) 357) 30) 5 (COPOLYMER (1: 2) (DP1R32D61U) 3) (DP1R32	1) TYPE A	(UNII: 74G4	Stre DIMETHYL	ngth FUMARATI	240 Stre	ngth
DIMU UNU CEL CEC CRC D&C FD& FER GEL MAC MET POT SHEI SHEI TAL TIT/ TRIF	ETHYL FUN 445IUB1PX8/ MONIA (UNII LULOSE, M DSCARMELL CYELLOW ROSOFERR ATIN (UNII: SNESIUM S' FHACRYLIC FHACRYLIC FHACRYLIC CON DIOXI C (UNII: 75E ANIUM DIOX C (UNII: 75E ANIUM DIOX ETHYL CITF DOLLCT CHOR OT	MARAT R) gredi I: 5138 II: 500 COSE 3 COSE 3	Ingredier E (UNII: F02303MNI2 ents (1) Q19F1X) RYSTALLINE (UNII: SODIUM (UNII: M28G) G (UNII: 355%505Q3 G (UNII: 355%505Q3 G (UNII: 477VE193A8) IDE (UNII: 30097M613 C (UNII: 355%507M613 C (UNIII) C (UNII: 355%507M613 C (UNIII) C (UNII: 355%507M613	nt Name 2) (MONOMETHYL FI ngredient Nam 2) (MONOMETHYL FI ngredient Nam 2) (DP1R32D61U) 2) (DP1R32D61U) 2) (DP1R32D61U) 357) 30) 5 (COPOLYMER (1: 2) (DP1R32D61U) 3) (DP1R32	1) TYPE A	(UNII: 74G4	Stre DIMETHYL	ngth FUMARATI	240 Stre 	ngth
DIM UNII: AMIN CEL CRC D&C FD& FER GEL MAC MET PRO SHE SILI TAL FRO SHE SILI TAL FOO SHE SILI TAL FOO SHE SILI	ETHYL FUN 44510B1PX80 MONIA (UNII LULOSE, M DSCARMELI CYELLOW ROSOFERR ATIN (UNII: SNESIUM S' THACRYLIC THACRYLIC THACRYLIC THACRYLIC CON DIOXI C (UNII: 75E ANIUM DIOXI C	MARAT R) gredi I: 5138 II: 500 COSE 3 COSE 3	Ingredier E (UNII: F02303MNI2 ents (21951x) CRYSTALLINE (UNII: M280C 5001UM (UNII: M280C 5001UM (UNII: M280C 5001UM (UNII: M280C 5001UM (UNII: M280C 501UM (UNII: M280C 501UM (UNII: M280C 501UM (UNII: M280C 1000 (UNII: M280C 1000 (UNII: M280C 1000 (UNII: M280C 1000 (UNII: M280C 1000 (UNII: M280C 1000 (UNII: S000C 1000 (UNII: S000C 1000 (UNII: S15100C) 1000 (UNII: S296QXD6UM) 1000 (UNII: S296QXD6UM)	nt Name 2) (MONOMETHYL FI ngredient Nam 2) (MONOMETHYL FI ngredient Nam 2) (DP1R32D61U) 2) (DP1R32D61U) 2) (DP1R32D61U) 357) 30) 5 (COPOLYMER (1: 2) (DP1R32D61U) 3) (DP1R32	1) TYPE A	(UNII: 74G4 Score Size	Stre DIMETHYL LV5T8J) R6TH13)	ngth FUMARATI	240 Stre	ngth
DIMUUNIII Ina AMIN CELL CRC D&C FD& FER GEL MAC MET PRO SHE SILI TTAL TRIE PRO SHE SILI TTAL TRIE PRO SHE SILI TTAL	ETHYL FUN 445IUB1PX8/ MONIA (UNII LULOSE, M DSCARMELI CYELLOW ROSOFERR ATIN (UNII: SINESIUM S' THACRYLIC THACRYLIC THACRYLIC CASSIUM HY PYLENE G LLAC (UNII: CON DIOXI C (UNII: 75E ANIUM DIOX C (UNII: 75E C (MARAT R) gredi I: 5138 II: 500 COSE 3 COSE 3	Ingredier E (UNII: F02303MNI2 ents (1) Q19F1X) RYSTALLINE (UNII: SODIUM (UNII: M28G) G (UNII: 355%505Q3 G (UNII: 355%505Q3 G (UNII: 477VE193A8) IDE (UNII: 30097M613 C (UNII: 355%507M613 C (UNIII) C (UNII: 355%507M613 C (UNIII) C (UNII: 355%507M613	nt Name 2) (MONOMETHYL FI ngredient Nam 2) (MONOMETHYL FI ngredient Nam 2) (DP1R32D61U) 2) (DP1R32D61U) 2) (DP1R32D61U) 357) 30) 5 (COPOLYMER (1: 2) (DP1R32D61U) 3) (DP1R32	1) TYPE A	(UNII: 74G4	Stre DIMETHYL LV5T8J) R6TH13)	ngth FUMARATI	240 Stre 	ngth
DIMUUNIII Ina AMIN CELL CRC D&C FD& FER GEL MAC MET PRO SHE SILI TTAL TRIE PRO SHE SILI TTAL TRIE PRO SHE SILI TTAL	ETHYL FUN 44510B1PX80 MONIA (UNII LULOSE, M DSCARMELI CYELLOW ROSOFERR ATIN (UNII: SNESIUM S' THACRYLIC THACRYLIC THACRYLIC THACRYLIC CON DIOXI C (UNII: 75E ANIUM DIOXI C	MARAT R) gredi I: 5138 II: 500 COSE 3 COSE 3	Ingredier E (UNII: F02303MNI2 ents (1) Q19F1X) RYSTALLINE (UNII: SODIUM (UNII: M28G) G (UNII: 355%505Q3 G (UNII: 355%505Q3 G (UNII: 477VE193A8) IDE (UNII: 30097M613 C (UNII: 355%507M613 C (UNIII) C (UNII: 355%507M613 C (UNIII) C (UNII: 355%507M613	nt Name 2) (MONOMETHYL FI ngredient Nam 2) (MONOMETHYL FI ngredient Nam 2) (DP1R32D61U) 2) (DP1R32D61U) 2) (DP1R32D61U) 357) 30) 5 (COPOLYMER (1: 2) (DP1R32D61U) 3) (DP1R32	1) TYPE A	(UNII: 74G4 Score Size	Stre DIMETHYL LV5T8J) R6TH13)	ngth FUMARATI	240 Stre	ngth
DIM UNII: AMIN CEL CRC D&C FD& FER GEL MAC MET PRO SHE SILI TAL TRIE PRO SHE SILI TAL TRIE PRO SHE SILI TAL TRIE SHA FER	ETHYL FUN 445IUB1PX8/ MONIA (UNII LULOSE, M DSCARMELI CYELLOW ROSOFERR ATIN (UNII: SINESIUM S' THACRYLIC THACRYLIC THACRYLIC CASSIUM HY PYLENE G LLAC (UNII: CON DIOXI C (UNII: 75E ANIUM DIOX C (UNII: 75E C (MARAT R) gredi I: 5138 II: 500 COSE 3 COSE 3	Ingredier E (UNII: F02303MNI2 ents (1) Q19F1X) RYSTALLINE (UNII: SODIUM (UNII: M28G) G (UNII: 355%505Q3 G (UNII: 355%505Q3 G (UNII: 477VE193A8) IDE (UNII: 30097M613 C (UNII: 355%507M613 C (UNIII) C (UNII: 355%507M613 C (UNIII) C (UNII: 355%507M613	nt Name 2) (MONOMETHYL FI ngredient Nam 2) (MONOMETHYL FI ngredient Nam 2) (DP1R32D61U) 2) (DP1R32D61U) 2) (DP1R32D61U) 357) 30) 5 (COPOLYMER (1: 2) (DP1R32D61U) 3) (DP1R32	1) TYPE A	(UNII: 74G4 Score Size	Stre DIMETHYL LV5T8J) R6TH13)	ngth FUMARATI	240 Stre	ngth
DIM UNII: AMN CELL CRC FD& FER GEL MAC FD& FER GEL MAC FD& SHE SILI TAL TAL TAL TAL TAL TAL TAL TAL TAL	ETHYL FUN 4550B1PX8/ MONIA (UNII LULOSE, M SSCARMELL SYELLOW ROSOFERR ATIN (UNII: SNESIUM S' FHACRYLIC FHACRYLIC FHACRYLIC CON DIOXI C (UNII: 75E ANIUM DIOX ETHYL CITF DOUCT Ch or spe vor itains	MARAT R) gredi I: 5138 II: 500 COSE 3 COSE 3	Ingredier E (UNII: F02303MNI2 ents (1) Q19F1X) RYSTALLINE (UNII: SODIUM (UNII: M28C) O (UNII: 355%505 G (UNII: 477VE193A8) IDE (UNII: 355%507 IDE (UNII: 70097M613 C (UNII: 355%507 IDE (UNII: 70097M613 C (UNII: 355%507 IDE (UNII: 70097M613 C (UNII: 355%507 IDE (UNII: 70097M613 C (UNII: 55%507 IDE (UNII: 35%507 IDE (UNIII) IDE (UNII: 35%507 IDE (UNII: 35%507 IDE (UNII: 3	nt Name 2) (MONOMETHYL FI ngredient Nam 2) (MONOMETHYL FI ngredient Nam 2) (DP1R32D61U) 2) (DP1R32D61U) 2) (DP1R32D61U) 357) 30) 5 (COPOLYMER (1: 2) (DP1R32D61U) 3) (DP1R32	1) TYPE A	(UNII: 74G4 Score Size	Stre DIMETHYL LV5T8J) R6TH13)	ngth FUMARATI	240 Stre	ngth
DIM UNII: AMN CELL CRC FD& FER GEL MAC FD& FER GEL MAC FD& SHE SILI TAL TRIF TAL TRIF Sha Flav Con	ETHYL FUN 455/UB1PX8/ 455/UB1PX8/ 457/UB1P	MARAT R) gredi I: 5138 II: 500 COSE 3 COSE 3	Ingredier E (UNII: F02303MNI2 ents (1) Q19F1X) RYSTALLINE (UNII: SODIUM (UNII: M28C) O (UNII: 355%505 G (UNII: 477VE193A8) IDE (UNII: 355%507 IDE (UNII: 70097M613 C (UNII: 355%507 IDE (UNII: 70097M613 C (UNII: 355%507 IDE (UNII: 70097M613 C (UNII: 355%507 IDE (UNII: 70097M613 C (UNII: 55%507 IDE (UNII: 35%507 IDE (UNIII) IDE (UNII: 35%507 IDE (UNII: 35%507 IDE (UNII: 3	nt Name 2) (MONOMETHYL FI ngredient Nam 2) (MONOMETHYL FI ngredient Nam 2) (DP1R32D61U) 2) (DP1R32D61U) 2) (DP1R32D61U) 357) 30) 5 (COPOLYMER (1: 2) (DP1R32D61U) 3) (DP1R32	1) TYPE A MER (1:1)	UNII: 7464 Score Size Imprint	Code	ngth FUMARATI	 240 Stre 3 4 5 5 5 5 7 	ngth
DIM UNII: AMN CELL CRC FD& FER GEL MAC FD& FER GEL MAC FD& SHE SILI TAL TAL TAL TAL TAL TAL TAL TAL TAL	ETHYL FUN 44510B1PX80 MONIA (UNII LULOSE, M DSCARMELL CYELLOW ROSOFERR ATIN (UNII: SNESIUM S' FHACRYLIC FHACRYLIC FHACRYLIC FACRYLIC CON DIOXI C (UNII: 75E ANIUM DIOX C (UNII: 75E ANIUM DIOX C (UNII: 75E ANIUM DIOX C (UNII: 75E ANIUM DIOX C (UNII: 75E COULT CH OF COULT CH COULT CH CH COULT CH CH CH CH CH CH CH CH CH CH CH CH CH C	MARAT R) gredi I: 5138 II: 500 COSE 3 COSE 3	Ingredier E (UNII: F02303MN/2 ents Q19F1X) RYSTALLINE (UNII: SODIUM (UNII: M280 (UNII: 355V50503 5 (UNII: M77VE193A8) IDE (UNII: XM0M87F: 10327L) TE (UNII: 70097M613 5 (UNII: M77VE193A8) IDE (UNII: XM0M87F: 10327L) TE (UNII: 70097M613 5 (UNII: M77VE193A8) IDE (UNII: M77VE193A8) IDE (UNII: M77VE193A8) IDE (UNII: S55V5029167V3 (IDE (UNII: 6259167V3 (IDE (UNIII)) (IDE (UNII: 6259167V3 (IDE (UNII)) (IDE (UNII: 625	nt Name () (MONOMETHYL FI () () () () () () () () () () () () ()	1) TYPE A MER (1:1)	UNII: 7464 Score Size Imprint (Code	ngth FUMARATI	240 Stre stre stre stre stre stre stre stre stre	ngth
DIM UNII: Ina AMM CEL CRO D&C FDS FER GEL MAC MET MET PRO SHE SILI TAL TRIE PRO SHE SILI TAL TRIE PRO SHE SILI TAL TRIE PRO SHE SILI TAL	ETHYL FUN 455/UB1PX8/ 455/UB1PX8/ 457/UB1P	MARAT R) gredi I: 51380 Glose S No. 10 / NO. 6 NIC OX 2G86Q TEARA ACID - YOROX LYCOL 46N10 DE (UN YOROX LYCOL 46N10 (DE (UN YOROX X LYCOL 46N10 (DE (UN YOROX X LYCOL 40 (DE (UN YOROX X LYCOL 40 (DE (UN YOROX X LYCOL 40 (DE (UN YOROX X LYCOL 40 (DE (UN YOROX X LYCOL 40 (DE (UN YOROX X LYCOL 40 (DE (UN YOROX X DE (UN YOROX X LYCOL 40 (DE (UN YOROX X LYCOL 40 (DE (UN X) X LYCOL 40 (DE (UN X) X LYCOL 40 (DE (UN X) X X X X X X X X X X X X X X X X X X	Ingredier E (UNII: F02303MN/2 ents Q19F1X) RYSTALLINE (UNII: 30 JUM (UNII: M28C 30 JUM (UNII: 355%50/303 5 (UNII: 355%50/303 5 (UNII: 377VE193A8) 10E (UNII: 370097M613 5 (UNII: 370097M613 10E (UNII: 70097M613 10E (UNIII) 10E (UNII: 70097M613 10E (UNII: 70097M613 10E (UNI	nt Name nt Name 2) (MONOMETHYL FI ngredient Nam (OP1R32D61U) D11HH48) (G) (3) 357) 30) E COPOLYMER (1: CRYLATE COPOLY BM4T) (Monowith Body) W(Body)	1) TYPE A MER (1:1)	UNII: 7464 Score Size Imprint	Code	ngth FUMARATI	 240 Stre 3 4 5 5 5 5 7 	ngth
DIM UNII: Ina AMM CEL CRO D&C FDS FER GEL MAC MET MET PRO SHE SILI TAL TRIE PRO SHE SILI TAL TRIE PRO SHE SILI TAL TRIE PRO SHE SILI TAL	ETHYL FUN 44510B1PX80 MONIA (UNII LULOSE, M DSCARMELL CYELLOW ROSOFERR ATIN (UNII: SNESIUM S' FHACRYLIC FHACRYLIC FHACRYLIC FACRYLIC CON DIOXI C (UNII: 75E ANIUM DIOX C (UNII: 75E ANIUM DIOX C (UNII: 75E ANIUM DIOX C (UNII: 75E ANIUM DIOX C (UNII: 75E COULT CH OF COULT CH COULT CH CH COULT CH CH CH CH CH CH CH CH CH CH CH CH CH C	MARAT R) gredi I: 51384 IICROC LOSE S NO. 100 VO. 6 RCO XI 2G86Q TEARA ACID ACID ACID YDROX VDROX VYOL VYOL VYOL VYOL AGID YE C/ AGID YE C/ 46 in	Ingredier E (UNII: F02303MM/2 ents Q19F1X) RYSTALLINE (UNII: SODIUM (UNII: M286 (UNII: 477VE193A8) IDE (UNII: 55X9V2)7 ITE (UNII: 50C9Q167V3 (IDE (UNII: WZH3C48 (UNII: 6DC9Q167V3 IDE (UNII: 477VE193A8) IDE (UNII: 477VE193A8) IDE (UNII: 50C9Q167V3 IDE (UNII: 50C9Q167V3 IDE (UNII: 50C9Q167V3 IDE (UNII: 50C9Q167V3 IDE (UNII: 15FIX9V2)P) U) U) III: 15FIX9V2)P) JNII: 15FIX9V2)P) JNII: 8Z96QXD6UM) Eteristics ELLOW (Cap) , YELLO APSULE Package D4 1 BOTTLE; Type 0: N	nt Name nt Name 2) (MONOMETHYL FI ngredient Nam (OP1R32D61U) D11HH48) (G) (3) 357) 30) E COPOLYMER (1: CRYLATE COPOLY BM4T) (Monowith Body) W(Body)	1) TYPE A MER (1:1)	UNII: 7464 Score Size Imprint (Code	ngth FUMARATI	240 Stre stre stre stre stre stre stre stre stre	ngth
DIM UNII Ina AMN CEL CRC CRC FD& FER GEL MAC MET POT SHE SILI TAL POT SHE SILI TAL POT Coli Sha Flav Con Pac A H TT/ TRIF	ETHYL FUN 44510B1PX80 MONIA (UNII LULOSE, M DSCARMELL CYELLOW ROSOFERR ATIN (UNII: SNESIUM S' FHACRYLIC FHACRYLIC FHACRYLIC FACRYLIC CON DIOXI C (UNII: 75E ANIUM DIOX C (UNII: 75E ANIUM DIOX C (UNII: 75E ANIUM DIOX C (UNII: 75E ANIUM DIOX C (UNII: 75E COULT CH OF COULT CH COULT CH CH COULT CH CH CH CH CH CH CH CH CH CH CH CH CH C	MARAT R) gredi I: 51380 Glose S No. 10 / NO. 6 NIC OX 2G86Q TEARA ACID - YOROX LYCOL 46N10 DE (UN YOROX LYCOL 46N10 (DE (UN YOROX X LYCOL 46N10 (DE (UN YOROX X LYCOL 40 (DE (UN YOROX X LYCOL 40 (DE (UN YOROX X LYCOL 40 (DE (UN YOROX X LYCOL 40 (DE (UN YOROX X LYCOL 40 (DE (UN YOROX X LYCOL 40 (DE (UN YOROX X DE (UN YOROX X LYCOL 40 (DE (UN YOROX X LYCOL 40 (DE (UN X) X LYCOL 40 (DE (UN X) X X X X X X X X X X X X X X X X X X	Ingredier E (UNII: F02303MM/2 ents Q19F1X) RYSTALLINE (UNII: SODIUM (UNII: M286 (UNII: 477VE193A8) IDE (UNII: 55X9V2)7 ITE (UNII: 50C9Q167V3 (IDE (UNII: WZH3C48 (UNII: 6DC9Q167V3 IDE (UNII: 477VE193A8) IDE (UNII: 477VE193A8) IDE (UNII: 50C9Q167V3 IDE (UNII: 50C9Q167V3 IDE (UNII: 50C9Q167V3 IDE (UNII: 50C9Q167V3 IDE (UNII: 15FIX9V2)P) U) U) III: 15FIX9V2)P) JNII: 15FIX9V2)P) JNII: 8Z96QXD6UM) Eteristics ELLOW (Cap) , YELLO APSULE Package D4 1 BOTTLE; Type 0: N	nt Name nt Name 2) (MONOMETHYL FI ngredient Nam (OP1R32D61U) D11HH48) (G) (3) 357) 30) E COPOLYMER (1: CRYLATE COPOLY BM4T) (Monowith Body) W(Body)	1) TYPE A MER (1:1)	UNII: 7464 Score Size Imprint (Code	ngth FUMARATI	240 Stre stre stre stre stre stre stre stre stre	ngth
DIM UNII: UNII: CRC CRC FD& FER GEL MAC FD& FER GEL MAC FD& SILI TRIE SILI TRIE SILI TRIE SILI TRIE SHA COI SHA FIAN COI SHA FIAN COI SHA FIAN COI SHA FIAN COI SHA FIAN COI SHA SHA COI SHA SHA COI SHA SHA COI SHA SHA SHA COI SHA SHA SHA SHA SHA SHA SHA SHA SHA SHA	ETHYL FUN 44510B1PX80 MONIA (UNII LULOSE, M DSCARMELL CYELLOW ROSOFERR ATIN (UNII: SNESIUM S' FHACRYLIC FHACRYLIC FHACRYLIC FHACRYLIC CON DIOXI C (UNII: 75E ANIUM DIOX C (UNII: 75E ANIUM DIOX C (UNII: 75E ANIUM DIOX C (UNII: 75E COULT CH OF COULT CH COULT CH OF COULT CH COULT CH CH COULT CH CH CH CH CH CH CH CH CH CH CH CH CH C	MARAT R) gredi I: 5138 IICROC LICROC LOSE S NO. 100 YOROX 2G86Q TEARA ACID ACID ACID YDROX VDROX VYOL VYOL VYOL VYOL AGID YE C/ AGID YE C/ AGID AGID YDROX YE C/ AGID AGID YE YE C/ AGID AGID AGID YE C/ AGID AGID AGID AGID AGID AGID AGID AGID AGID <td>Ingredier E (UNII: F02303MM/2 ents Q19F1X) RYSTALLINE (UNII: SODIUM (UNII: M286 (UNII: 477VE193A8) IDE (UNII: 55X9V2)7 ITE (UNII: 50C9Q167V3 (IDE (UNII: WZH3C48 (UNII: 6DC9Q167V3 IDE (UNII: 477VE193A8) IDE (UNII: 477VE193A8) IDE (UNII: 50C9Q167V3 IDE (UNII: 50C9Q167V3 IDE (UNII: 50C9Q167V3 IDE (UNII: 50C9Q167V3 IDE (UNII: 15FIX9V2)P) U) U) III: 15FIX9V2)P) JNII: 15FIX9V2)P) JNII: 8Z96QXD6UM) Eteristics ELLOW (Cap) , YELLO APSULE Package D4 1 BOTTLE; Type 0: N</td> <td>nt Name nt Name 2) (MONOMETHYL FI ngredient Nam (OP1R32D61U) D11HH48) (G) (3) 357) 30) E COPOLYMER (1: CRYLATE COPOLY BM4T) (Monowith Body) W(Body)</td> <td>1) TYPE A MER (1:1)</td> <td>UNII: 7464 Score Size Imprint (</td> <td>Code</td> <td>ngth FUMARATI</td> <td>240 Stre stre stre stre stre stre stre stre stre</td> <td>ngth</td>	Ingredier E (UNII: F02303MM/2 ents Q19F1X) RYSTALLINE (UNII: SODIUM (UNII: M286 (UNII: 477VE193A8) IDE (UNII: 55X9V2)7 ITE (UNII: 50C9Q167V3 (IDE (UNII: WZH3C48 (UNII: 6DC9Q167V3 IDE (UNII: 477VE193A8) IDE (UNII: 477VE193A8) IDE (UNII: 50C9Q167V3 IDE (UNII: 50C9Q167V3 IDE (UNII: 50C9Q167V3 IDE (UNII: 50C9Q167V3 IDE (UNII: 15FIX9V2)P) U) U) III: 15FIX9V2)P) JNII: 15FIX9V2)P) JNII: 8Z96QXD6UM) Eteristics ELLOW (Cap) , YELLO APSULE Package D4 1 BOTTLE; Type 0: N	nt Name nt Name 2) (MONOMETHYL FI ngredient Nam (OP1R32D61U) D11HH48) (G) (3) 357) 30) E COPOLYMER (1: CRYLATE COPOLY BM4T) (Monowith Body) W(Body)	1) TYPE A MER (1:1)	UNII: 7464 Score Size Imprint (Code	ngth FUMARATI	240 Stre stre stre stre stre stre stre stre stre	ngth

	AND 10105	Citation		Da	le	D	ate
NDA	ANDA21022	5		10/31/2020			
	_	_					
Marketing				Markatir	a Ctort	Marka	ting End
Marketing Category	Арриса	tion Number or Mor Citation	iograph	Marketir Da			ting End Date
NDA	ANDA21022	6		10/31/2020			
		re					
imethyl fumarate	e capsule, de	alayed release					
Product Infor	mation						
Product Type		HUMAN PRESCRIPTION	DRUG	Item Code	(Source)	NDC:6	8180-776
Route of Admini	stration	ORAL					
Active Ingredi	ent/Active	Moiety					
	Ing	redient Name				is of ngth	Streng
DIMETHYL FUMAR	ATE (UNII: FO2:	303MNI2) (MONOMETHYL	- FUMARATE			FUMARATE	120 mg
JNII:45IUB1PX8R)					BINETITE		120
nactive Ingre	dianta						
nactive myre	ulents	Ingredient Na	ame				Strengt
MMONIA (UNII: 51							
		E (UNII: OP1R32D61U)					
DOCCADMELLOC							
		II: M28OL1HH48)					
O&C YELLOW NO.	10 (UNII: 355V	5USQ3G)					
D&C YELLOW NO. D&C YELLOW NO	10 (UNII: 355V D. 6 (UNII: H77V	5USQ3G) EI93A8)					
D&C YELLOW NO. D&C YELLOW NO FERROSOFERRIC (10 (UNII: 355V 0.6 (UNII: H77V DXIDE (UNII: XM	5USQ3G) EI93A8)					
D&C YELLOW NO. D&C YELLOW NO FERROSOFERRIC (GELATIN (UNII: 2G8	10 (UNII: 355W D. 6 (UNII: H77V DXIDE (UNII: XM 86QN327L)	5USQ3G) EI93A8) 10M87F357)					
D&C YELLOW NO. D&C YELLOW NO ERROSOFERRIC GELATIN (UNII: 2G8 MAGNESIUM STEA	10 (UNII: 355W). 6 (UNII: H77V DXIDE (UNII: XM 36QN327L) RATE (UNII: 700	5USQ3G) EI93A8) 10M87F357)	(1:1) TYPE	A (UNII: NX761	_V5T8J)		
D&C YELLOW NO. FD&C YELLOW NO FERROSOFERRIC (GELATIN (UNII: 2G8 MAGNESIUM STEA METHACRYLIC ACI	10 (UNII: 355W 0. 6 (UNII: H77V DXIDE (UNII: XM 36QN327L) RATE (UNII: 700 ID - ETHYL AC	/5USQ3G) EI93A8) 10M87F357) 297M6I30)					
D&C YELLOW NO. D&C YELLOW NO FERROSOFERRIC (GELATIN (UNII: 2G8 MAGNESIUM STEA METHACRYLIC ACI POTASSIUM HYDR	10 (UNII: 355%) 0. 6 (UNII: H77V DXIDE (UNII: XM 36QN327L) IRATE (UNII: 700 ID - ETHYL AC ID - METHYL M OXIDE (UNII: W	6USQ3G) EI93A8) 10M87F357) D97M6I30) RYLATE COPOLYMER IETHACRYLATE COPO Z H3C48M4T)					
D&C YELLOW NO. FD&C YELLOW NO FERROSOFERRIC (GELATIN (UNII: 208 MAGNESIUM STEA METHACRYLIC ACI METHACRYLIC ACI POTASSIUM HYDR PROPYLENE GLYC	10 (UNII: 355% 0. 6 (UNII: H77V DXIDE (UNII: XM 36QN327L) 37ATE (UNII: 700 10 - ETHYL AC 10 - METHYL M OXIDE (UNII: W OL (UNII: 6DC90	6USQ3G) EI93A8) 10M87F357) D97M6I30) RYLATE COPOLYMER IETHACRYLATE COPO Z H3C48M4T)					
D&C YELLOW NO. FD&C YELLOW NO FERROSOFERRIC (GELATIN (UNII: 208 MAGNESIUM STEA METHACRYLIC ACI METHACRYLIC ACI POTASSIUM HYDR PROPYLENE GLYC SHELLAC (UNII: 466	10 (UNII: 355V 0. 6 (UNII: H77V DXIDE (UNII: XM 860N327L) RATE (UNII: 701 10 - ETHYL ACI 10 - METHYL M OXIDE (UNII: WO OL (UNII: 60C90 107B710)	6USQ3G) EI93A8) 10M87F357) D97M6I30) RYLATE COPOLYMER IETHACRYLATE COPO Z H3C48M4T) Q167V3)					
D&C YELLOW NO. FD&C YELLOW NO FERROSOFERRIC (GELATIN (UNII: 2G8 MAGNESIUM STEA METHACRYLIC ACI METHACRYLIC ACI POTASSIUM HYDR PROPYLENE GLYC SHELLAC (UNII: 466 SILICON DIOXIDE	10 (UNII: 355V 0. 6 (UNII: H77V DXIDE (UNII: XM 46QN327L) IRATE (UNII: 701 10 - ETHYL ACI 10 - METHYL M OXIDE (UNII: 40C91 4107B710) (UNII: ETJ7Z 6XB	6USQ3G) EI93A8) 10M87F357) D97M6I30) RYLATE COPOLYMER IETHACRYLATE COPO Z H3C48M4T) Q167V3)					
D&C YELLOW NO. D&C YELLOW NO. FEROSOFERRIC (SELATIN (UNII: 2G8 MAGNESIUM STEA METHACRYLIC ACI OOTASSIUM HYDR PROPYLENE GLYC: SHELLAC (UNII: 466 SILICON DIOXIDE FALC (UNII: 75EV7)4	10 (UNII: 355V 0. 6 (UNII: H77V DXIDE (UNII: XM 46QN327L) IRATE (UNII: 701 ID - HTHYL AC OXIDE (UNII: 60C9(VI07B710) (UNII: ETJ7Z 6XB 4R1U)	6USQ3G) EI93A8) 10M87F357) D97M6I30) RYLATE COPOLYMER IETHACRYLATE COPO Z H3C48M4T) Q167V3) U4)					
D&C YELLOW NO. FD&C YELLOW NO. FERROSOFERRIC (GELATIN (UNII: 2G8 MAGNESIUM STEA METHACRYLIC ACI POTASSIUM HYDR PROPYLENE GLYC: SHELLAC (UNII: 46h SILICON DIOXIDE FALC (UNII: 7SEV7) FITANIUM DIOXIDI	10 (UNII: 355V 0. 6 (UNII: H77V DXIDE (UNII: XM 46QN327L) IRATE (UNII: 701 ID - ETHYL ACI ID - METHYL ACI OXIDE (UNII: 60C90 1107B710) (UNII: ETJ7Z 6XB 4R1U) E (UNII: 15FIX9V	6USQ3G) EI93A8) 10M87F357) 997M6I30) RYLATE COPOLYMER I IETHACRYLATE COPO ZH3C48M4T) Q167V3) U4) 2JP)					
D&C YELLOW NO. D&C YELLOW NO. FEROSOFERRIC (SELATIN (UNII: 2G8 MAGNESIUM STEA METHACRYLIC ACI OOTASSIUM HYDR PROPYLENE GLYC: SHELLAC (UNII: 466 SILICON DIOXIDE FALC (UNII: 75EV7)4	10 (UNII: 355V 0. 6 (UNII: H77V DXIDE (UNII: XM 46QN327L) IRATE (UNII: 701 ID - ETHYL ACI ID - METHYL ACI OXIDE (UNII: 60C90 1107B710) (UNII: ETJ7Z 6XB 4R1U) E (UNII: 15FIX9V	6USQ3G) EI93A8) 10M87F357) 997M6I30) RYLATE COPOLYMER I IETHACRYLATE COPO ZH3C48M4T) Q167V3) U4) 2JP)					
D&C YELLOW NO. D&C YELLOW NO. FEROSOFERRIC (SELATIN (UNII: 208 MAGNESIUM STEA METHACRYLIC ACI POTASSIUM HYDR PROPYLENE GLYC SHELLAC (UNII: 46M SILICON DIOXIDE FALC (UNII: 75EV7)/ TITANIUM DIOXIDE FRIETHYL CITRATI	10 (UNII: 355V 0. 6 (UNII: H77V DXIDE (UNII: XM 460N327L) IRATE (UNII: 701 DI - ETHYL ACI DI - METHYL ACI DI - METHYL MO OXIDE (UNII: 60C90 V107B710) (UNII: ETJ7Z 6XB 4R1U) E (UNII: 15FIX9V E (UNII: 8Z960)	6USQ3G) EI93A8) 10M87F357) 997M6I30) RYLATE COPOLYMER I IETHACRYLATE COPO ZH3C48M4T) Q167V3) U4) 2JP)					
Dec YELLOW NO. FDec YELLOW NO. FERROSOFERRIC (SELATIN (UNII: 208 MAGNESIUM STEA METHACRYLIC ACI POTASSIUM HYDR PROPYLENE GLYC SHELLAC (UNII: 466 SILICON DIOXIDE FALC (UNII: 75EV7) FITANIUM DIOXIDI RIETHYL CITRATI	10 (UNII: 355V 0. 6 (UNII: H77V DXIDE (UNII: XM 460N327L) IRATE (UNII: 701 10 - ETHYL ACI 10 - METHYL ACI 10 - METHYL MO OXIDE (UNII: 701 10 - METHYL MO OXIDE (UNII: 701 10 - TTYL 10 - T	6USQ3G) EI93A8) 10M87F357) 0997M6I30) RYLATE COPOLYMER IETHACRYLATE COPO ZH3C48M4T) 2167V3) U4) 2JP) CD6UM)		1) (UNII: 74G4			50076
Dec YELLOW NO. Dec YELLOW NO. FERROSOFERRIC (SELATIN (UNII: 2G8 MAGNESIUM STEA METHACRYLIC ACI POTASSIUM HYDR PROPYLENE GLYC SHELLAC (UNII: 46M SILICON DIOXIDE FALC (UNII: 7SEV7)/ FITANIUM DIOXIDE FRIETHYL CITRATI Product Chara Color	10 (UNII: 355V 0. 6 (UNII: H77V DXIDE (UNII: XM 460N327L) IRATE (UNII: 701 10 - ETHYL ACI 10 - METHYL ACI 10 - METHYL MO OXIDE (UNII: 701 10 - METHYL MO OXIDE (UNII: 60C90 V107B710) (UNII: ETJ7Z 6XB 4R1U) E (UNII: 15FIX9V E (UNII: 8Z 960) ACTEPRISTICS YELLOW (Cap)	6USQ3G) EI93A8) 10M87F357) 997M6I30) RYLATE COPOLYMER I IETHACRYLATE COPO ZH3C48M4T) Q167V3) U4) 2JP)		1) (UNII: 74G4			score
Dec YELLOW NO. ERROSOFERRIC (SELATIN (UNII: 2G8 MAGNESIUM STEA METHACRYLIC ACI METHACRYLIC ACI POTASSIUM HYDR PROPYLENE GLYC SHELLAC (UNII: 46M SILICON DIOXIDE FALC (UNII: 7SEV7)/ FITANIUM DIOXIDI FRIETHYL CITRATI Product Chara Color Shape	10 (UNII: 355V 0. 6 (UNII: H77V DXIDE (UNII: XM 460N327L) IRATE (UNII: 701 10 - ETHYL ACI 10 - METHYL ACI 10 - METHYL MO OXIDE (UNII: 701 10 - METHYL MO OXIDE (UNII: 701 10 - TTYL 10 - T	6USQ3G) EI93A8) 10M87F357) 0997M6I30) RYLATE COPOLYMER IETHACRYLATE COPO ZH3C48M4T) 2167V3) U4) 2JP) CD6UM)		1) (UNII: 74G4 Score Size	R6TH13)	19n	
Dec YELLOW NO. Dec YELLOW NO. ERROSOFERRIC (SELATIN (UNII: 268 MAGNESIUM STEA METHACRYLIC ACI WETHACRYLIC ACI POTASSIUM HYDR PROPYLENE GLYC SHELLAC (UNII: 466 SILICON DIOXIDE FALC (UNII: 75EV7) (TTANIUM DIOXIDE FILLAC (UNII: 75EV7) (TTANIUM	10 (UNII: 355V 0. 6 (UNII: H77V DXIDE (UNII: XM 460N327L) IRATE (UNII: 701 10 - ETHYL ACI 10 - METHYL ACI 10 - METHYL MO OXIDE (UNII: 701 10 - METHYL MO OXIDE (UNII: 60C90 V107B710) (UNII: ETJ7Z 6XB 4R1U) E (UNII: 15FIX9V E (UNII: 8Z 960) ACTEPRISTICS YELLOW (Cap)	6USQ3G) EI93A8) 10M87F357) 0997M6I30) RYLATE COPOLYMER IETHACRYLATE COPO ZH3C48M4T) 2167V3) U4) 2JP) CD6UM)		1) (UNII: 74G4	R6TH13)	19n	nm
Dec YELLOW NO. EDEC YELLOW NO. ERROSOFERRIC (SELATIN (UNII: 208 MAGNESIUM STEA METHACRYLIC ACI VETHACRYLIC ACI VOTASSIUM HYDR PROPYLENE GLYC SHELLAC (UNII: 466 SILICON DIOXIDE FALC (UNII: 75EV7) TANIUM DIOXIDE FALC (UNII: 75EV7) TANIUM DIOXIDE FALC (UNII: 75EV7) TANIUM DIOXIDE FALC (UNII: 75EV7) SILICON DIOXIDE FALC (UNII: 75EV7) SILICON DIOXIDE SILICON DI	10 (UNII: 355V 0. 6 (UNII: H77V DXIDE (UNII: XM 460N327L) IRATE (UNII: 701 10 - ETHYL ACI 10 - METHYL ACI 10 - METHYL MO OXIDE (UNII: 701 10 - METHYL MO OXIDE (UNII: 60C90 V107B710) (UNII: ETJ7Z 6XB 4R1U) E (UNII: 15FIX9V E (UNII: 8Z 960) ACTEPRISTICS YELLOW (Cap)	6USQ3G) EI93A8) 10M87F357) 0997M6I30) RYLATE COPOLYMER IETHACRYLATE COPO ZH3C48M4T) 2167V3) U4) 2JP) CD6UM)		1) (UNII: 74G4 Score Size	R6TH13)	19n	nm
D&C YELLOW NO. FD&C YELLOW NO. FERROSOFERRIC (SELATIN (UNII: 2G8 MAGNESIUM STEA METHACRYLIC ACI POTASSIUM HYDR PROPYLENE GLYC SHELLAC (UNII: 46M SILICON DIOXIDE FALC (UNII: 7SEV7) FITANIUM DIOXIDE FRIETHYL CITRATI	10 (UNII: 355V 0. 6 (UNII: H77V DXIDE (UNII: XM 460N327L) IRATE (UNII: 701 10 - ETHYL ACI 10 - METHYL ACI 10 - METHYL MO OXIDE (UNII: 701 10 - METHYL MO OXIDE (UNII: 60C90 V107B710) (UNII: ETJ7Z 6XB 4R1U) E (UNII: 15FIX9V E (UNII: 8Z 960) ACTEPRISTICS YELLOW (Cap)	6USQ3G) EI93A8) 10M87F357) 0997M6I30) RYLATE COPOLYMER IETHACRYLATE COPO ZH3C48M4T) 2167V3) U4) 2JP) CD6UM)		1) (UNII: 74G4 Score Size	R6TH13)	19n	nm
Dec YELLOW NO. FD&C YELLOW NO. FD&C YELLOW NO. FERROSOFERRIC (SELATIN (UNII: 208 MAGNESIUM STEA METHACRYLIC ACI POTASSIUM HYDR PROPYLENE GLYC: HELLAC (UNII: 45EV7)/ HELLAC (UNII: 45EV7)/ HELLAC (UNII: 45EV7)/ TTANIUM DIOXIDI TRIETHYL CITRATI Product Chara Color Shape Shape Source Charace Shape S	10 (UNII: 355V 0. 6 (UNII: H77V DXIDE (UNII: XM 46QN327L) IRATE (UNII: 701 ID - ETHYL ACI 10 - ETHYL ACI 10 - NETHYL A	6USQ3G) EI93A8) 10M87F357) 0997M6I30) RYLATE COPOLYMER IETHACRYLATE COPO ZH3C48M4T) 2167V3) U4) 2JP) CD6UM)		1) (UNII: 74G4 Score Size	ode Start	19n LU; Market	nm D76 ting End
Dec YELLOW NO. Dec YELLOW NO. Dec YELLOW NO ERROSOFERRIC (SELATIN (UNII: 268 MAGNESIUM STEA METHACRYLIC ACI VETHACRYLIC ACI VETHACRYLIC ACI VOTASSIUM HYDR PROPYLENE GLYC SILLCON DIOXIDE TALC (UNII: 456 TANIUM DIOXIDE TALC (UNII: 75EV7) TANIUM DIOXIDE TALC (UNII: 75EV7) TANIUM DIOXIDE TRIETHYL CITRATI Product Chara Color Shape Tavor Contains Packaging # Item Code NDC:68180-776-	10 (UNII: 355V 0. 6 (UNII: H77V DXIDE (UNII: XM 46QN327L) IRATE (UNII: 701 ID - ETHYL ACI 10 - ETHYL ACI 10 - NETHYL A	6USQ3G) EI93A8) 10M87F357) 2097M6I30) RYLATE COPOLYMER 1 EITHACRYLATE COPOLYMER 7 EITHACRYLATE COPOLYMER 1 2167V3) U4) 2199 (D6UM) , WHITE (Body)	LYMER (1:)	1) (UNII: 74G4 Score Size Imprint C	ode Start	19n LU; Market	nm D76
Dec YELLOW NO. FDec YELLOW NO. FEROSOFERRIC (SELATIN (UNII: 268 MAGNESIUM STEA METHACRYLIC ACI POTASSIUM HYDR PROPYLENE GLYC SHELLAC (UNII: 466 SILICON DIOXIDE FALC (UNII: 75EV7)/ FITANIUM DIOXIDI FRIETHYL CITRATI Product Chara Color Shape Tavor Contains Packaging f Item Code NDC:68180-776- 14	10 (UNII: 355W 0. 6 (UNII: H77V DXIDE (UNII: H77V DXIDE (UNII: XM 460N327L) IRATE (UNII: 701 D0 - ETHYL ACI 10 - METHYL ACI 10 - METHY	6USQ3G) EI93A8) 10M87F357) 2097M6I30) RYLATE COPOLYMER 1 EITHACRYLATE COPOLYMER 7 EITHACRYLATE COPOLYMER 1 2167V3) U4) 2199 (D6UM) , WHITE (Body)	LYMER (1:3	1) (UNII: 74G4 Score Size Imprint C Marketing Date	ode Start	19n LU; Market	nm D76 ting End
Dec YELLOW NO. Dec YELLOW NO. Dec YELLOW NO ERROSOFERRIC (SELATIN (UNII: 268 MAGNESIUM STEA METHACRYLIC ACI VETHACRYLIC ACI VETHACRYLIC ACI VOTASSIUM HYDR PROPYLENE GLYC SILLCON DIOXIDE TALC (UNII: 456 TANIUM DIOXIDE TALC (UNII: 75EV7) TANIUM DIOXIDE TALC (UNII: 75EV7) TANIUM DIOXIDE TRIETHYL CITRATI Product Chara Color Shape Tavor Contains Packaging # Item Code NDC:68180-776-	10 (UNII: 355W 0. 6 (UNII: H77V DXIDE (UNII: XH 36QN327L) IRATE (UNII: 701 ID - ETHYL AC ID - METHYL AC INI: 5772 6XB 400 CAPSULE Pac 1 in 1 CARTON	6USQ3G) EI93A8) 10M87F357) 2097M6I30) RYLATE COPOLYMER 1 ETHACRYLATE COPOLYMER 2H3C48M4T) 2167V3) U4) 21P) (2D6UM) (2D6UM) (2D6UM)	LYMER (1:3	1) (UNII: 74G4 Score Size Imprint C Marketing Date	ode Start	19n LU; Market	nm D76 ting End
Dec YELLOW NO. FD&C YELLOW NO. FEROSOFERRIC (SELATIN (UNII: 208 MAGNESIUM STEA METHACRYLIC ACI POTASSIUM HYDR PROPYLENE GLYC SHELLAC (UNII: 46M SILICON DIOXIDE FALC (UNII: 75EV7)/ FITANIUM DIOXIDE FILLAC (UNII: 75EV7)/ FILLAC (UNII: 75EV7)/ FILL	10 (UNII: 355V 0. 6 (UNII: H77V DXIDE (UNII: XM 10 (UNII: M 10 - ETHYL ACI 10 - ETHYL ACI 10 - ETHYL ACI 10 - METHYL M OXIDE (UNII: 701 001 (UNII: 60090 10 - METHYL M OXIDE (UNII: 15F1X9V E (UNII: 15F1X9V E (UNII: 15F1X9V E (UNII: 8296QX ACTERISTICS YELLOW (Cap) CAPSULE 1 in 1 CARTON 14 in 1 BOTTL Product	6USQ3G) EI93A8) 10M87F357) 097M6I30) RYLATE COPOLYMER IETHACRYLATE COPOL ZH3C48M4T) 2167V3) U4) 2JP) CD6UM) , WHITE (Body) ; WHITE (Body)	LYMER (1:3	1) (UNII: 74G4 Score Size Imprint C Marketing Date	ode Start	19n LU; Market	nm D76 ting End
AC YELLOW NO. DAC YELLOW NO. ERROSOFERRIC (SELATIN (UNII: 208 MAGNESIUM STEA METHACRYLIC ACI POTASSIUM HYDR PROPYLENE GLYC HELLAC (UNII: 466 SILICON DIOXIDE FALC (UNII: 75EV7)/ ITTANIUM DIOXIDE Contains Packaging Item Code INDC:68180-776- 14 Marketing	10 (UNII: 355W 0. 6 (UNII: H77V DXIDE (UNII: H77V DXIDE (UNII: XM 460M327L) IRATE (UNII: 701 D0 - ETHYL ACI 10 - METHYL ACI 10 - METHY	6USQ3G) EI93A8) 10M87F357) PYLATE COPOLYMER 1 EIFTHACRYLATE COPOLYMER 2H3C48M4T) 2167V3) U4) 2JP) Cb6UM) , WHITE (Body) ; WHITE (Body) Ekage Description I E; Type 0: Not a Combin	LYMER (1:3	1) (UNII: 74G4 Score Size Imprint C 0/31/2020	ode Start	19n LU; Market D	nm D76 Ling End ate
Dec YELLOW NO. FD&C YELLOW NO. FEROSOFERRIC (SELATIN (UNII: 208 MAGNESIUM STEA METHACRYLIC ACI POTASSIUM HYDR PROPYLENE GLYC SHELLAC (UNII: 46M SILICON DIOXIDE FALC (UNII: 75EV7)/ FITANIUM DIOXIDE FILLAC (UNII: 75EV7)/ FILLAC (UNII: 75EV7)/ FILL	10 (UNII: 355W 0. 6 (UNII: H77V DXIDE (UNII: H77V DXIDE (UNII: XM 460M327L) IRATE (UNII: 701 D0 - ETHYL ACI 10 - METHYL ACI 10 - METHY	6USQ3G) EI93A8) 10M87F357) 097M6I30) RYLATE COPOLYMER IETHACRYLATE COPOL ZH3C48M4T) 2167V3) U4) 2JP) CD6UM) , WHITE (Body) ; WHITE (Body)	LYMER (1:3	1) (UNII: 74G4 Score Size Imprint C Marketing Date	ode Start	19n LU; Market D.	nm D76 ting End
Dec YELLOW NO. EDec YELLOW NO. EDec YELLOW NO ERROSOFERRIC (SELATIN (UNII: 2068) MAGNESIUM STEA METHACRYLIC ACI VOTASSIUM HYDR POPYLENE GLYC SILICON DIOXIDE SILICON DIOXIDE TANIUM DIOXIDE TANIUM DIOXIDE TANIUM DIOXIDE TANIUM DIOXIDE TANIUM DIOXIDE Color Sihape Havor Contains Packaging Item Code NDC:68180-776- 14 Marketing Marketing	10 (UNII: 355W 0. 6 (UNII: H77V DXIDE (UNII: H77V DXIDE (UNII: XM 460M327L) IRATE (UNII: 701 D0 - ETHYL ACI 10 - METHYL ACI 10 - METHY	6USQ3G) EI93A8) 10M87F357) 2097M6[30) RYLATE COPOLYMER I ETHACRYLATE COPOLYMER IETHACRYLATE COPOLYMER 2167V3) 2167V3) 219) 206UM) ; WHITE (Body) ; WHITE (Body)	LYMER (1:3	1) (UNII: 74G4 Size Imprint C 0/31/2020 Marketing	ode Start	19n LU; Market D.	nm D76 ting End ate
AC YELLOW NO. DAC YELLOW NO. DAC YELLOW NO ERROSOFERRIC (SELATIN (UNII: 2084 MAGNESIUM STEA METHACRYLIC ACI POTASSIUM HYDR POPYLENE GLYC: INTANIUM DIOXIDE ALC (UNII: 45EV7) TTANIUM DIOXIDE RETHYL CITRATI Product Chara Color Shape Contains Packaging f Item Code NDC:68180-776-14 Marketing Category	10 (UNII: 355W 0. 6 (UNII: H77V DXIDE (UNII: XH 36QN327L) IRATE (UNII: 701 D - ETHYL AC 1D - METHYL M OXIDE (UNII: 701 D - THYL AC 1D - METHYL M OXIDE (UNII: 707 (UNII: 60290 107770) (UNII: 15F1X9V E (UNII: 15F1X9V	6USQ3G) EI93A8) 10M87F357) 2097M6[30) RYLATE COPOLYMER I ETHACRYLATE COPOLYMER IETHACRYLATE COPOLYMER 2167V3) 2167V3) 219) 206UM) ; WHITE (Body) ; WHITE (Body)	LYMER (1:3	1) (UNII: 74G4 Score Size Imprint C 0/31/2020 Marketin Date	ode Start	19n LU; Market D.	nm D76 ting End ate

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68180-777
Route of Administration	ORAL		
Active Ingredient/Active	Moiety		
			-

	Ingredient Name			isis or rength	Strengt
DIMETHYL FUMAR INII:45IUB1PX8R)	ATE (UNII: FO2303MNI2) (MONOMETHYL FUMA	RATE -	DIMETHY	L FUMARATE	240 mg
nactive Ingre	dients				
	Ingredient Name				Strengt
AMMONIA (UNII: 51	38Q19F1X)				
ELLULOSE, MICR	OCRYSTALLINE (UNII: OP1R32D61U)				
ROSCARMELLOS	E SODIUM (UNII: M28OL1HH48)				
	10 (UNII: 35SW5USQ3G)				
	0.6 (UNII: H77VEI93A8)				
ERROSOFERRIC (DXIDE (UNII: XM0M87F357)				
GELATIN (UNII: 2G8					
	RATE (UNII: 70097M6I30)				
	D - ETHYL ACRYLATE COPOLYMER (1:1)				
		< (1:1) (JNII: /4G4R61H13)		
	OXIDE (UNII: WZ H3C48M4T)				
SHELLAC (UNII: 46N	OL (UNII: 6DC9Q167V3)				
HELLAC (UNII: 400					
ULICON DIOXIDE					
TALC (UNII: 7SEV7J4	IR1U)				
SILICON DIOXIDE (TALC (UNII: 7SEV7)4 TITANIUM DIOXIDE TRIETHYL CITRATE	IR1U)				
TALC (UNII: 7SEV7J4 TITANIUM DIOXIDE	IR1U) E (UNII: 15FIX9V2JP)				
FALC (UNII: 7SEV7]4 FITANIUM DIOXIDE	IR1U) E (UNII: 15FIX9V2JP)				
TALC (UNII: 75EV7)4 TTANIUM DIOXIDE TRIETHYL CITRATE	RTU) E (UNII: 15FIX9V2JP) E (UNII: 8Z96QXD6UM)				
rale (UNII: 75EV7)4 FITANIUM DIOXIDE FRIETHYL CITRATE Product Chara	RTU) E (UNII: 15FIX9V2JP) E (UNII: 8Z96QXD6UM)		Score	no	score
rale (UNII: 75EV7)4 FITANIUM DIOXIDE FRIETHYL CITRATE Product Chara Color	IRIU) E (UNII: 15FIX9V2JP) E (UNII: 8Z96QXD6UM) Acteristics		Score Size	no 21r	
rale (UNII: 75EV7) FITANIUM DIOXIDE FRIETHYL CITRATE Product Chara Color Shape	IRIU) E (UNII: 15FIX9V2JP) E (UNII: 8Z96QXD6UM) E (UNII: 8Z96QXD6UM) E (UNII: 8Z96QXD6UM) E (UNII: 8Z96QXD6UM) E (UNII: 8Z96QXD6UM)			21r	
rale (UNII: 75EV7) FITANIUM DIOXIDE FRIETHYL CITRATE Product Chara Color Shape Flavor	IRIU) E (UNII: 15FIX9V2JP) E (UNII: 8Z96QXD6UM) E (UNII: 8Z96QXD6UM) E (UNII: 8Z96QXD6UM) E (UNII: 8Z96QXD6UM) E (UNII: 8Z96QXD6UM)		Size	21r	nm
FALC (UNII: 7SEV7]4 FITANIUM DIOXIDE	IRIU) E (UNII: 15FIX9V2JP) E (UNII: 8Z96QXD6UM) E (UNII: 8Z96QXD6UM) E (UNII: 8Z96QXD6UM) E (UNII: 8Z96QXD6UM) E (UNII: 8Z96QXD6UM)		Size	21r	nm
rale (UNII: 75EV7) FITANIUM DIOXIDE FRIETHYL CITRATE Product Chara Color Shape Flavor	IRIU) E (UNII: 15FIX9V2JP) E (UNII: 8Z96QXD6UM) E (UNII: 8Z96QXD6UM) E (UNII: 8Z96QXD6UM) E (UNII: 8Z96QXD6UM) E (UNII: 8Z96QXD6UM)		Size	21r	nm
rALC (UNII: 75EV7)4 FITANIUM DIOXIDE FRIETHYL CITRATE Product Chara Color Shape -lavor Contains	IRIU) E (UNII: 15FIX9V2JP) E (UNII: 8Z96QXD6UM) E (UNII: 8Z96QXD6UM) E (UNII: 8Z96QXD6UM) E (UNII: 8Z96QXD6UM) E (UNII: 8Z96QXD6UM)		Size	21r	nm
rale (UNII: 75EV7) ritanium dioxide rriethyl citrate Product Chara Color shape elavor Contains Packaging	IRIU) E (UNII: 15FIX9V2JP) E (UNII: 8Z96QXD6UM) E (UNII: 8Z96QXD6UM) E (UNII: 8Z96QXD6UM) E (UNII: 8Z96QXD6UM) E (UNII: 8Z96QXD6UM)	Μ	Size Imprint Code arketing Start	21r LU; Market	nm D77 t ing End
rate (UNII: 75EV7)4 ranium dioxida rater view of the second rater v	IRIU) E (UNII: 15FIX9V2JP) E (UNII: 8Z96QXD6UM) ACTERISTICS YELLOW (Cap), YELLOW (Body) CAPSULE		Size Imprint Code	21r LU; Market	nm D77
ALC (UNII: 75EV7)4 ITANIUM DIOXIDE RIETHYL CITRATE Product Chara Color hape lavor contains Packaging tem Code NDC:68180-777- 07	IRIU) E (UNII: 15FIX9V2JP) E (UNII: 8Z96QXD6UM) Acteristics YELLOW (Cap) , YELLOW (Body) CAPSULE Package Description 1 in 1 CARTON 60 in 1 BOTTLE; Type 0: Not a Combination		Size Imprint Code arketing Start Date	21r LU; Market	nm D77 ting End
rALC (UNII: 75EV7)4 FITANIUM DIOXIDE FIRIETHYL CITRATE Product Chara Color Shape Flavor Contains Packaging flem Code NDC:68180-777- 1	RIU) (UNII: 15FIX9V2JP) (UNII: 8Z96QXD6UM) Acteristics YELLOW (Cap) , YELLOW (Body) CAPSULE Package Description 1 in 1 CARTON 60 in 1 BOTTLE; Type 0: Not a Combination Product		Size Imprint Code arketing Start Date	21r LU; Market	nm D77 t ing End
rate (UNII: 75EV7)4 ritanium dioxida ritethyl citrate Product Chara Color Shape lavor Contains Packaging # Item Code 1 Noc68180-777- 1 Marketing	RIU) E (UNII: 15FIX9V2JP) E (UNII: 8Z96QXD6UM) Acteristics YELLOW (Cap), YELLOW (Body) CAPSULE Package Description 1 in 1 CARTON 60 in 1 BOTTLE; Type 0: Not a Combination Product Information	10/3	Size Imprint Code arketing Start Date	21r LU; Market D	nm D77 ting End ate
rALC (UNII: 75EV7)4 FITANIUM DIOXIDE FRIETHYL CITRATE Product Chara Color Shape Flavor Contains Packaging # Item Code 1 NDC:68180-777- 07	RIU) (UNII: 15FIX9V2JP) (UNII: 8Z96QXD6UM) Acteristics YELLOW (Cap) , YELLOW (Body) CAPSULE Package Description 1 in 1 CARTON 60 in 1 BOTTLE; Type 0: Not a Combination Product	10/3	Size Imprint Code arketing Start Date	Market D	nm D77 ting End

Labeler - Lupin Pharmaceuticals, Inc. (089153071)

Registrant - Lupin Atlantis Holdings SA (483965500)

 Establishment

 Name
 Address
 ID/FEI
 Business Operations

 Aizant Drug Research Solutions Pvt Ltd
 650372951
 ANALYSIS(68180-776, 68180-777, 68180-778), MANUFACTURE(68180-776, 68180-777, 68180-777), 68180-777), 68180-777, 68180-777, 68180-777, 68180-777, 68180-777, 68180-777, 68180-777, 68180-777, 68180-777, 68180-777, 68180-777)

Revised: 12/2021

Lupin Pharmaceuticals, Inc.