#### METHOCARBAMOL- methocarbamol tablets tablet, coated Proficient Rx LP

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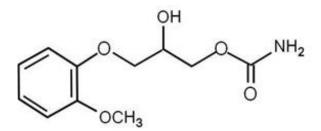
**Methocarbamol Tablets** 

**Rx Only** 

#### DESCRIPTION

Methocarbamol tablet, USP, a carbamate derivative of guaifenesin, is a central nervous system (CNS) depressant with sedative and musculoskeletal relaxant properties.

The chemical name of methocarbamol is 1,2-Propanediol,3-(2-methoxyphenoxy)-,1-Carbamate,( $\pm$ )-.(or) ( $\pm$ )-3-(o-Methoxyphenoxy)-1,2-Propanediol 1-carbamate and has the empirical formula C11H15NO5. Its molecular weight is 241.24g/mol. The structural formula is shown below.



Methocarbamol is a white powder, sparingly soluble in water and in chloroform, soluble in alcohol (only with heating), insoluble in benzene and in n-hexane.

Methocarbamol tablets, USP are available as 500 mg and 750 mg tablets for oral administration.

Methocarbamol tablets, USP 500 mg are light orange colored, round shaped film coated tablets debossed with "G" above the score line on one side and "500" on other side.

Methocarbamol tablets, USP 750 mg are light orange colored, caplet shaped film coated tablets debossed with "G" on one side and "750" on other side.

Methocarbamol tablets, USP 500 mg and 750 mg contain the following inactive ingredients: colloidal silicon dioxide, maize starch, povidone, sodium lauryl sulfate, sodium starch glycolate, and stearic acid.

The tabets are coated with Aquarius Prime which contains FD&C yellow 6, hydroxypropylcellulose, hypromellose, polysorbate 80, propylene glycol, and titanium dioxide

# **CLINICAL PHARMACOLOGY**

The mechanism of action of methocarbamol in humans has not been established, but may be due to general central nervous system (CNS) depression. It has no direct action

on the contractile mechanism of striated muscle, the motor end plate or the nerve fiber.

#### Pharmacokinetics

In healthy volunteers, the plasma clearance of methocarbamol ranges between 0.20 and 0.80 L/h/kg, the mean plasma elimination half-life ranges between 1 and 2 hours, and the plasma protein binding ranges between 46% and 50%.

Methocarbamol is metabolized via dealkylation and hydroxylation. Conjugation of methocarbamol also is likely. Essentially all methocarbamol metabolites are eliminated in the urine. Small amounts of unchanged methocarbamol also are excreted in the urine.

#### **Special Populations**

#### Elderly

The mean ( $\pm$  SD) elimination half-life of methocarbamol in elderly healthy volunteers (mean ( $\pm$  SD) age, 69 ( $\pm$  4) years) was slightly prolonged compared to a younger (mean ( $\pm$  SD) age, 53.3 ( $\pm$  8.8) years), healthy population (1.5 ( $\pm$  0.4) hours versus 1.1 ( $\pm$  0.27) hours, respectively). The fraction of bound methocarbamol was slightly decreased in the elderly versus younger volunteers (41 to 43% versus 46 to 50%, respectively).

#### Renally impaired

The clearance of methocarbamol in 8 renally-impaired patients on maintenance hemodialysis was reduced about 40% compared to 17 normal subjects, although the mean ( $\pm$  SD) elimination half-life in these two groups was similar: 1.2 ( $\pm$  0.6) versus 1.1 ( $\pm$ 0.3) hours, respectively.

#### Hepatically impaired

In 8 patients with cirrhosis secondary to alcohol abuse, the mean total clearance of methocarbamol was reduced approximately 70% compared to that obtained in 8 ageand weight-matched normal subjects. The mean ( $\pm$  SD) elimination half-life in the cirrhotic patients and the normal subjects was 3.38 ( $\pm$  1.62) hours and 1.11 ( $\pm$  0.27) hours, respectively. The percent of methocarbamol bound to plasma proteins was decreased to approximately 40 to 45% compared to 46 to 50% in the normal subjects.

#### **INDICATIONS & USAGE**

Methocarbamol tablets, USP are indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions. The mode of action of methocarbamol has not been clearly identified, but may be related to its sedative properties. Methocarbamol does not directly relax tense skeletal muscles in man.

#### CONTRAINDICATIONS

Methocarbamol tablets are contraindicated in patients hypersensitive to methocarbamol or to any of the tablet components.

#### WARNINGS

Since methocarbamol may possess a general CNS depressant effect, patients receiving

Methocarbamol tablets should be cautioned about combined effects with alcohol and other CNS depressants.

Safe use of Methocarbamol tablets has not been established with regard to possible adverse effects upon fetal development. There have been reports of fetal and congenital abnormalities following in utero exposure to methocarbamol. Therefore, Methocarbamol tablets should not be used in women who are or may become pregnant and particularly during early pregnancy unless in the judgment of the physician the potential benefits outweigh the possible hazards (see **PRECAUTIONS, Pregnancy**).

## Use in Activities Requiring Mental Alertness

Methocarbamol may impair mental and/or physical abilities required for performance of hazardous tasks, such as operating machinery or driving a motor vehicle. Patients should be cautioned about operating machinery, including automobiles, until they are reasonably certain that methocarbamol therapy does not adversely affect their ability to engage in such activities.

# PRECAUTIONS

## **INFORMATION FOR PATIENTS**

Patients should be cautioned that methocarbamol may cause drowsiness or dizziness, which may impair their ability to operate motor vehicles or machinery.

Because methocarbamol may possess a general CNS-depressant effect, patients should be cautioned about combined effects with alcohol and other CNS depressants.

# **DRUG INTERACTIONS**

See **WARNINGS** and **PRECAUTIONS** for interaction with CNS drugs and alcohol.

Methocarbamol may inhibit the effect of pyridostigmine bromide. Therefore, methocarbamol should be used with caution in patients with myasthenia gravis receiving anticholinesterase agents.

# **DRUG & OR LABORATORY TEST INTERACTIONS**

Methocarbamol may cause color interference in certain screening tests for 5hydroxyindoleacetic acid (5-HIAA) using nitrosonaphthol reagent and in screening tests for urinary vanillylmandelic acid (VMA) using the Gitlow method.

# **CARCINOGENESIS & MUTAGENESIS & IMPAIRMENT OF FERTILITY**

Long-term studies to evaluate the carcinogenic potential of methocarbamol have not been performed. No studies have been conducted to assess the effect of methocarbamol on mutagenesis or its potential to impair fertility.

#### PREGNANCY

#### **Teratogenic Effects**

Pregnancy Category C

Animal reproduction studies have not been conducted with methocarbamol. It is also not known whether methocarbamol can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Methocarbamol tablets should be given to a pregnant woman only if clearly needed.

Safe use of methocarbamol tablet has not been established with regard to possible adverse effects upon fetal development. There have been reports of fetal and congenital abnormalities following in utero exposure to methocarbamol. Therefore, Methocarbamol tablets should not be used in women who are or may become pregnant and particularly during early pregnancy unless in the judgment of the physician the potential benefits outweigh the possible hazards (see **WARNINGS**).

# NURSING MOTHERS

Methocarbamol and/or its metabolites are excreted in the milk of dogs; however, it is not known whether methocarbamol or its metabolites are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when methocarbamol tablets are administered to a nursing woman.

#### PEDIATRIC USE

Safety and effectiveness of methocarbamol tablets in pediatric patients below the age of 16 have not been established.

# **ADVERSE REACTIONS**

Adverse reactions reported coincident with the administration of methocarbamol include:

Body as a whole: Anaphylactic reaction, angioneurotic edema, fever, headache

Cardiovascular system: Bradycardia, flushing, hypotension, syncope, thrombophlebitis

Digestive system: Dyspepsia, jaundice (including cholestatic jaundice), nausea and vomiting

Hemic and lymphatic system: Leukopenia

Immune system: Hypersensitivity reactions

Nervous system: Amnesia, confusion, diplopia, dizziness or lightheadedness, drowsiness, insomnia, mild muscular incoordination, nystagmus, sedation, seizures(including grand mal), vertigo

Skin and special senses: Blurred vision, conjunctivitis, nasal congestion, metallic taste, pruritus, rash, Urticaria

To report SUSPECTED ADVERSE REACTIONS, contact Granules USA, Inc. at 1-877-770-3183 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

# OVERDOSAGE

Limited information is available on the acute toxicity of methocarbamol. Overdose of methocarbamol is frequently in conjunction with alcohol or other CNS depressants and includes the following symptoms: nausea, drowsiness, blurred vision, hypotension, seizures, and coma.

In post-marketing experience, deaths have been reported with an overdose of methocarbamol alone or in the presence of other CNS depressants, alcohol or psychotropic drugs.

## Treatment

Management of overdose includes symptomatic and supportive treatment. Supportive measures include maintenance of an adequate airway, monitoring urinary output and vital signs, and administration of intravenous fluids if necessary. The usefulness of hemodialysis in managing overdose is unknown.

# **DOSAGE & ADMINISTRATION**

Methocarbamol Tablets, USP 500 mg – Adults: Initial dosage: 3 tablets 4 times daily Maintenance dosage: 2 tablets 4 times daily Methocarbamol Tablets, USP 750 mg – Adults: Initial dosage: 2 tablets 4 times daily Maintenance dosage: 1 tablet every 4 hours or 2 tablets three times daily

Six grams a day are recommended for the first 48 to 72 hours of treatment. (For severe conditions 8 grams a day may be administered). Thereafter, the dosage can usually be reduced to approximately 4 grams a day.

# HOW SUPPLIED

Methocarbamol tablets, USP 750 mg are light orange colored, capletshaped film coated tablets debossed with "G" on one side and "750" on other side.

Bottles of 20 tablets NDC 71205-068-20 Bottles of 30 tablets NDC 71205-068-30 Bottles of 40 tablets NDC 71205-068-40 Bottles of 45 tablets NDC 71205-068-45 Bottles of 60 tablets NDC 71205-068-60 Bottles of 90 tablets NDC 71205-068-90 Store between 20°C and 25°C (68°F and 77° F) [see USP Controlled Room Temperature]. Dispense in tight container. Manufactured for: Granules USA, Inc. Parsippany, NJ 07054 Toll-free: 1-877-770-3183

Manufactured by: Granules India Limited Hyderabad-500 081 Made in India

Issued: January 2017 Repackaged By: Proficient Rx LP

Thousand Oaks, CA 91320

# PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

ProficientRx NDC 71205-068-30	) Packaged By: Proficient Rx LP Thousand Oaks, CA 91320	
Methocarbamol 750mg	Methocarbamol 750mg #30 Tablets SN# MASTE Lot #:00000 Exp:00/00/00 NDC 71205-068-30	
<b>#30 Tablets</b> Each film-coated tablet contains: Methocarbamol USP, 750 mg	Methocarbarnol 750mg #30 Tablets SN# MASTE Lot #:00000 Exp:00/00/00 NDC 71205-068-30	
Light orange colored, caplet shaped film coated tablets debossed with "G" on one side and "750" on other side. Product ID: QM006830	Methocarbamol 750mg #30 Tablets SN#MASTER Lot #:00000 Exp:00/00/00 NDC 71205-068-30	
Mfr. By: Granules India Limited Hyderabad - 500 081, India MADE IN INDIA Store between 20°-25°C (68°-77°F) Keep medication out of the reach of children	GTIN: 00371205068301 SN# MASTER Exp. 00/00/00 Lot #:00000	

# **METHOCARBAMOL**

methocarbamol tablets tablet, coated

#### **Product Information**

Draduct Type

HUMAN PRESCRIPTION

Item Code

NDC:71205-068(NDC:70010-

SILICON DIOXIDE (UNII: ET/72 6X8U4)       Image: Size and Siz	Product I	pe	DRUG		(Source)	770)				
Ingredient Name       Basis of Strength         METHOCARBAMOL (UNII: 1250D7737X) (METHOCARBAMOL - UNII:1250D7737X)       METHOCARBAMOL         Inactive Ingredients       Ingredient Name       Ingredient Name         SILICON DIOXIDE (UNII: ETJ726X8U4)       STARCH, CORN (UNII: 08232V735))       Ingredient Name         SODIUM LAURYL SULFATE (UNII: 3586B5141))       SODIUM SULFATE (UNII: 3586B5141))       SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)       STEARIC ACID (UNII: 4LV7265AP)         FDaC YELLOW NO. 6 (UNII: H77YEI9388)       HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)       HYPROXELOSE 2910 (6 MPA.S) (UNII: 0VZ 8WG20P6)         POROPYLENE GLYCOL (UNII: 60ZP392G8H)       PROPYLENE GLYCOL (UNII: 60ZP392G8H)       PROPYLENE         PROPYLENE GLYCOL (UNII: 5FK39V2JP)       Imprint Code       G;750         Color       orange       Score       no score         Shape       CAPSULE       Size       19mm         Flavor       Imprint Code       G;750       G;750         Contains       Ing 1 BOTTLE; Type 0: Not a Combination       0%01/2018       Imprint Code         1       20C:71205-068       20 in 1 BOTTLE; Type 0: Not a Combination       07/02/2018       Imprint Code         3       NDC:71205-068       40 in 1 BOTTLE; Type 0: Not a Combination       07/02/2018       Improduct         4 </th <th>Route of</th> <th>dministratio</th> <th>n ORAL</th> <th></th> <th></th> <th></th> <th></th>	Route of	dministratio	n ORAL							
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METHOCARBAMOL (UNII: 1250D7737X) (METHOCARBAMOL - UNII: 1250D7737X) METHOCARBAMOL         Injective Ingredients         Injective Ingredient Name         SILICON DIOXIDE (UNII: ETJ7Z 6XBU4)         STARCH, CORN (UNII: ETJ7Z 6XBU4)         STARCH, CORN (UNII: ETJ7Z 6XBU4)         SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)         STEARIC ACID (UNII: 4ELV7Z 65AP)         FD&C YELLOW NO. 6 (UNII: H77YE!93A8)         HYPROMELLOSE 16000000 WAMW) (UNII: RFW2ET671P)         HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0VZ 8WG20P6)         POLYSORBATE 80 (UNII: 6DC90167V3)         TITANIUM DIOXIDE (UNII: 15FIX9V2JP)         FOCULE Characteristics         Color       orange       Score       no score         Solut K Characteristics         CAPSULE       Size       19mm         Product Characteristics         CAPSULE       Size       19mm         FIAVOR       Areckaging         #       Marketing Start       Marketing Start         NDC:71205-068       20 in 1 BOTTLE	Active Ingredient/Active Moiety									
Ingredients         Ingredient Name         SILICON DIOXIDE (UNII: ETJ/Z6X8U4)         STARCH, CORN (UNII: 08232NY35))         CROSPOVIDONE (UNII: 257830E561)         SODIUM LAURYL SULFATE (UNII: 368GB5141))         SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)         STEARIC ACID (UNII: 4LV7265AP)         FD&C YELLOW NO. 6 (UNII: H77VEI93A8)         HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFV2ET671P)         HYDROXYPROPYL CELLULOSE (000020167V3)         ITTANIUM DIOXIDE (UNII: 160C90167V3)         ITTANIUM DIOXIDE (UNII: 15FIX9V2)P)         Imprint Code         Score       no score			-				-			
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CROSPOVIDONE (UNII: 257830E561)       SODIUM LAURYL SULFATE (UNII: 368GB5141))       SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856j3G2A2)       STEARIC ACID (UNII: 4ELV7265AP)         FD&C YELLOW NO. 6 (UNII: H77VE193A8)       HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)       HYPROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)       HYPROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)         HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)       HYPROMELLOSE 2910 (6 MPA.5) (UNII: 0WZ 8WG20P6)       POLYSORBATE 80 (UNII: 60C90167V3)         PROPYLENE GLYCOL (UNII: 6DC90167V3)       TITANIUM DIOXIDE (UNII: 15FIX9V2JP)       no score         Solor       orange       Score       no score         Shape       CAPSULE       Size       19mm         Flavor       Imprint Code       G;750       G;750         Contains       CAPSULE       Size       19mm         *       Item Code       Package Description       Marketing Start Date       Marketing Start Date         NDC:71205-068:       20 in 1 BOTTLE; Type 0: Not a Combination 2007/02/2018       07/02/2018       07/02/2018	SILICON DI	DXIDE (UNII: ETJ	7Z6XBU4)							
SODIUM LAURYL SULFATE (UNII: 368GB5141))       SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856j3G2A2)       I         STEARIC ACID (UNII: 4ELV7Z 65AP)       FD&C YELLOW NO. 6 (UNII: H77VEI93A8)       I         HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)       HY         HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)       HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ 8WG20P6)       POLYSORBATE 80 (UNII: 6DC90167V3)         PROPYLENE GLYCOL (UNII: 6DC90167V3)       TITANIUM DIOXIDE (UNII: 15FIX9V2JP)       no score         Solor       orange       Score       no score         Shape       CAPSULE       Size       19mm         Flavor       Gr370       Imprint Code       G;750         V       V       Size       19mm         Flavor       08/01/2018       V       19mm         1       NDC:71205-068- 20 in 1 BOTTLE; Type 0: Not a Combination 20 (7/02/2018       08/01/2018       V         1       NDC:71205-068- 30 in 1 BOTTLE; Type 0: Not a Combination 20 (7/02/2018       07/02/2018       V         1       NDC:71205-068- 40 in 1 BOTTLE; Type 0: Not a Combination 20 (7/02/2018       07/02/2018       V         1       NDC:71205-068- 45 in 1 BOTTLE; Type 0: Not a Combination 20 (7/02/2018       07/02/2018       V         1       NDC:71205-068- 45 in 1 BOTTLE; Type 0: Not a Combination 45<	STARCH, C	<b>DRN</b> (UNII: 08232	2NY3SJ)							
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856)3G2A2)       I         STEARIC ACID (UNII: 4ELV7265AP)       I         FD&C YELLOW NO. 6 (UNII: H77VE193A8)       I         HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)       I         HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)       I         HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)       I         HYPROMELLOSE 2910 (6 MPA.S) (UNII: 00Z 8WG2DF)       I         POLYSORBATE 80 (UNII: 6DC793PZ 68H)       I         PROPYLENE GLYCOL (UNII: 6DC90167V3)       I         TITANIUM DIOXIDE (UNII: 15FIX9V2JP)       I         Product Characteristics       Inprint Code         Color       orange       Score       no score         Shape       CAPSULE       Size       19mm         Flavor       Imprint Code       G;750         Contains       I       Inprint Code       G;750         V       Stare       08/01/2018       I         1       NDC;71205-068-       20 in 1 BOTTLE; Type 0: Not a Combination       08/01/2018       I         20       NDC;71205-068-       30 in 1 BOTTLE; Type 0: Not a Combination       07/02/2018       I         3       NDC;71205-068-       40 in 1 BOTTLE; Type 0: Not a Combination       08/01/2018	CROSPOVI	<b>ONE</b> (UNII: 2578	330E561)							
STEARIC ACID (UNII: 4ELV7265AP)       FD&C YELLOW NO. 6 (UNII: H77VEI93A8)       FD         HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)       HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ 8WG20P6)       POLYSORBATE 80 (UNII: 60CP39Z G8H)       POLYSORBATE 80 (UNII: 60CP39Z G8H)         PROPYLENE GLYCOL (UNII: 60CP30 (UNII: 60C90167V3)       TITANIUM DIOXIDE (UNII: 15FIX39V2JP)       Import 100 (UNII: 15FIX39V2JP)       Import 100 (UNII: 15FIX39V2JP)         PROPYLENE GLYCOL (UNII: 15FIX39V2JP)       Orange       Score       no score         Shape       CAPSULE       Size       19mm         Flavor       Imprint Code       G;750         Contains       Imprint Code       G;750         V       Size       19mm         Flavor       Imprint Code       G;750         Contains       Imprint Code       G;750         V       Size       19mm         NDC:71205-068-       20 in 1 BOTTLE; Type 0: Not a Combination Product       08/01/2018       Imprint Code         NDC:71205-068-       30 in 1 BOTTLE; Type 0: Not a Combination Product       07/02/2018       Imprint Code       Imprint Code         NDC:71205-068-       40 in 1 BOTTLE; Type 0: Not a Combination Product       07/02/2018       Imprint Code       Imprint Code       Imprint Code         NDC:71205-068-       45 in 1 BOTTLE; Type			<b>*</b>							
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)       H177VE193A8)         HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)       H1         HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ 8WG20P6)       POLYSORBATE 80 (UNII: 60ZP39ZG8H)         PROPYLENE GLYCOL (UNII: 6DC9Q167V3)       TITANIUM DIOXIDE (UNII: 15FIX9V2JP)         Product Characteristics       orange         Score       no score         Shape       CAPSULE         Color       orange         Size       19mm         Flavor       CAPSULE         V       Imprint Code         G;750       G;750         Contains       NDC:71205-068-         20 in 1 BOTTLE; Type 0: Not a Combination Product       08/01/2018         NDC:71205-068-       30 in 1 BOTTLE; Type 0: Not a Combination Product       07/02/2018         NDC:71205-068-       40 in 1 BOTTLE; Type 0: Not a Combination Product       07/02/2018       07/02/2018         NDC:71205-068-       40 in 1 BOTTLE; Type 0: Not a Combination Product       07/02/2018       07/02/2018         NDC:71205-068-       40 in 1 BOTTLE; Type 0: Not a Combination Product       07/02/2018       07/02/2018         NDC:71205-068-       40 in 1 BOTTLE; Type 0: Not a Combination Product       07/02/2018       07/02/2018         NDC:71205-068-       40 in 1 BOTTLE; Typ	SODIUM ST	ARCH GLYCOLA	ATE TYPE A POTATO (U	JNII: 5856J3	G2A2)					
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)       H         HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ 8WG20P6)       POLYSORBATE 80 (UNII: 60C2P39ZG8H)       PROPYLENE GLYCOL (UNII: 60C9Q167V3)         PROPYLENE GLYCOL (UNII: 15C9Q2)P)       TITANIUM DIOXIDE (UNII: 15FX9V2)P)       Marketing Score       No score         Stape       Orange       Score       No score         Shape       CAPSULE       Size       19mm         Flavor       Imprint Code       G;750         Contains       Size       19mm         V       Product Characteristic       G;750         Prover       Size       19mm         Flavor       Imprint Code       G;750         Contains       Size       19mm         NDC:71205-068:       20 in 1 BOTTLE; Type 0: Not a Combination Product       08/01/2018       Marketing Start Date         NDC:71205-068:       30 in 1 BOTTLE; Type 0: Not a Combination Product       07/02/2018       Imprint Code       Imprint Code         NDC:71205-068:       40 in 1 BOTTLE; Type 0: Not a Combination Product       07/02/2018       Imprint Code       Imprint Code       Imprint Code         NDC:71205-068:       45 in 1 BOTTLE; Type 0: Not a Combination Product       07/02/2018       Imprint Code       Imprint Code       Imprint Code       Imprint Code <th></th> <th>•</th> <th></th> <th></th> <th></th> <th></th> <th></th>		•								
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ 8WG20P6)       Image: Constant of the state of the stat										
POLYSORBATE 80 (UNII: 6∪ZP39ZG8H)       Image       Image       Image       No score         Shape       CAPSULE       Size       19mm         Flavor       CAPSULE       Imprint Code       6;750         V       Size       19mm         Flavor       G;750       19mm         V       Marketing Start       Marketing Start         V       Package Description       08/01/2018       Marketing Start         1       NDC:71205-068-       20 in 1 BUTTLE; Type 0: Not a Combination Product       07/02/2018       01/02/018         2       NDC:71205-068-       30 in 1 BUTTLE; Type 0: Not a Combination Product       08/01/2018       01/2018         3       NDC:71205-068-       40 in 1 BUTTLE; Type 0: Not a Combination Product       08/01/2018       1         4       NDC:71205-068-       60 in 1 BUTTLE; Type 0: Not a Combination Product       08/01/2018       1         5       NDC:71205-068-       60 in 1 BUTTLE; Type 0: Not a Combination Product       08/01/2018       1					V2ET671P)					
PROPYLENE GLYCOL (UNII: 6DC9Q167V3) TITANIUM DIOXIDE (UNII: 15FIX9V2JP)         or ange       Score       no score         or ange       Score       no score         Shape       CAPSULE       Size       19mm         Flavor       CAPSULE       Size       Size         Product       Size       Size         Markeing Start       Markeing Start       Markeing Start       Size         J       20 in 1 BOTTLE; Type 0: Not a Combination       Of/02/2018 <th cols<="" th=""><th></th><th></th><th></th><th>0P6)</th><th></th><th></th><th></th></th>	<th></th> <th></th> <th></th> <th>0P6)</th> <th></th> <th></th> <th></th>				0P6)					
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)         Product Characteristics         orange       Score       no score         Size       19mm         Imprint Code       G;750         Flavor       GAPSULE       Size       19mm         Imprint Code       G;750         CAPSULE       Size       19mm         Flavor       G;750         CAPSULE       Imprint Code       G;750         Flavor       Marketing Start       Marketing Start         JUC:71205-068:       20 in 1 BOTTLE; Type 0: Not a Combination       08/01/2018         NDC:71205-068:       20 in 1 BOTTLE; Type 0: Not a Combination       07/02/2018         I NDC:71205-068:       20 in 1 BOTTLE; Type 0: Not a Combination       07/02/2018         Product       07/02/2018         I NDC:71205-068:       45 in 1 BOTTLE; Type 0: Not a Combination       08/01/2018         I NDC:71205-068:       45 in 1 BOTTLE; Type 0: Not										
Product Characteristics         orange       Score       no score         Shape       CAPSULE       Size       19mm         Flavor       GAPSULE       Size       19mm         Flavor       CAPSULE       Size       19mm         Flavor       G(750         Contains       Size       19mm         Marketing Start       G(750         Packaging         # Item Code       Package Description       Marketing Start       Marketing Start         DOC:71205-068-       20 in 1 BOTTLE; Type 0: Not a Combination       Product         INDC:71205-068-       30 in 1 BOTTLE; Type 0: Not a Combination       Product         Product       O7/02/2018         ADC:71205-068-       40 in 1 BOTTLE; Type 0: Not a Combination       O7/02/2018         ADC:71205-068-       40 in 1 BOTTLE; Type 0: Not a Combination       O7/02/2018         ADC:71205-068-       40 in 1										
Color         orange         Score         no score           Shape         CAPSULE         Size         19mm           Flavor         imprint Code         G;750           Contains			511/(3 ¥2ji )							
Color         orange         Score         no score           Shape         CAPSULE         Size         19mm           Flavor         imprint Code         G;750           Contains										
Shape       CAPSULE       Size       19mm         Flavor       Imprint Code       G;750         Contains       Indicating       Girage       Girage         #       Item Code       Package Description       Marketing Start Date       Marketing Start Date         1       NDC:71205-068- 20       20 in 1 BOTTLE; Type 0: Not a Combination Product       08/01/2018       08/01/2018         2       NDC:71205-068- 30       30 in 1 BOTTLE; Type 0: Not a Combination Product       07/02/2018       07/02/2018         3       NDC:71205-068- 40       40 in 1 BOTTLE; Type 0: Not a Combination Product       08/01/2018       08/01/2018         4       NDC:71205-068- 45       45 in 1 BOTTLE; Type 0: Not a Combination Product       08/01/2018       08/01/2018	Product	Characteris	tics							
Flavor       Imprint Code       G;750         G:750         Contains         Packaging         #       Item Code       Package Description       Marketing Start Date       Marketing Start Date         1       NDC:71205-068- 20 in 1 BOTTLE; Type 0: Not a Combination Product       08/01/2018       08/01/2018       Imprint Code         2       NDC:71205-068- 30 in 1 BOTTLE; Type 0: Not a Combination Product       07/02/2018       07/02/2018       Imprint Code         3       NDC:71205-068- 40 in 1 BOTTLE; Type 0: Not a Combination Product       07/02/2018       07/02/2018       Imprint Code         4       NDC:71205-068- 45 in 1 BOTTLE; Type 0: Not a Combination Product       08/01/2018       Imprint Code         5       NDC:71205-068- 60 in 1 BOTTLE; Type 0: Not a Combination Product       08/01/2018       Imprint Code	Color		orange Score			no	score			
Image: Second all second	Shape		CAPSULE	PSULE Size		19mm				
Item Code       Package Description       Marketing Start Date       Marketing Start Date         NDC:71205-068-       20 in 1 BOTTLE; Type 0: Not a Combination Product       08/01/2018       08/01/2018         NDC:71205-068-       30 in 1 BOTTLE; Type 0: Not a Combination Product       07/02/2018       07/02/2018         NDC:71205-068-       40 in 1 BOTTLE; Type 0: Not a Combination Product       07/02/2018       07/02/2018         NDC:71205-068-       40 in 1 BOTTLE; Type 0: Not a Combination Product       07/02/2018       07/02/2018         NDC:71205-068-       45 in 1 BOTTLE; Type 0: Not a Combination Product       08/01/2018       08/01/2018	Flavor			Imprint Code		G;	G;750			
#Item CodePackage DescriptionMarketing Start DateMarketing Start Date1NDC:71205-068- 2020 in 1 BOTTLE; Type 0: Not a Combination Product08/01/201808/01/20182NDC:71205-068- 3030 in 1 BOTTLE; Type 0: Not a Combination Product07/02/201807/02/20183NDC:71205-068- 4040 in 1 BOTTLE; Type 0: Not a Combination Product07/02/201807/02/20184NDC:71205-068- 4545 in 1 BOTTLE; Type 0: Not a Combination Product08/01/201808/01/20185NDC:71205-068- 60 in 1 BOTTLE; Type 0: Not a Combination Product08/01/201808/01/2018	Contains									
#Item CodePackage DescriptionMarketing Start DateMarketing Start Date1NDC:71205-068- 2020 in 1 BOTTLE; Type 0: Not a Combination Product08/01/201808/01/20182NDC:71205-068- 3030 in 1 BOTTLE; Type 0: Not a Combination Product07/02/201807/02/20183NDC:71205-068- 4040 in 1 BOTTLE; Type 0: Not a Combination Product07/02/201807/02/20184NDC:71205-068- 4545 in 1 BOTTLE; Type 0: Not a Combination Product08/01/201808/01/20185NDC:71205-068- 60 in 1 BOTTLE; Type 0: Not a Combination Product08/01/201808/01/2018										
#Item CodePackage DescriptionMarketing Start DateMarketing Start Date1NDC:71205-068- 2020 in 1 BOTTLE; Type 0: Not a Combination Product08/01/201808/01/20182NDC:71205-068- 3030 in 1 BOTTLE; Type 0: Not a Combination Product07/02/201807/02/20183NDC:71205-068- 4040 in 1 BOTTLE; Type 0: Not a Combination Product07/02/201807/02/20184NDC:71205-068- 4545 in 1 BOTTLE; Type 0: Not a Combination Product08/01/201808/01/20185NDC:71205-068- 60 in 1 BOTTLE; Type 0: Not a Combination Product08/01/201808/01/2018										
#Item CodePackage DescriptionDateD1NDC:71205-068- 2020 in 1 BOTTLE; Type 0: Not a Combination Product08/01/201808/01/20182NDC:71205-068- 3030 in 1 BOTTLE; Type 0: Not a Combination Product07/02/201807/02/20183NDC:71205-068- 4040 in 1 BOTTLE; Type 0: Not a Combination Product07/02/201807/02/20184NDC:71205-068- 4545 in 1 BOTTLE; Type 0: Not a Combination Product08/01/201808/01/20185NDC:71205-068- 60 in 1 BOTTLE; Type 0: Not a Combination Product08/01/201808/01/2018	Packagii	g				_				
1       20       Product       06/01/2018         2       NDC:71205-068- 30       30 in 1 BOTTLE; Type 0: Not a Combination Product       07/02/2018         3       NDC:71205-068- 40       40 in 1 BOTTLE; Type 0: Not a Combination Product       07/02/2018         4       NDC:71205-068- 45       45 in 1 BOTTLE; Type 0: Not a Combination Product       08/01/2018         5       NDC:71205-068- 60 in 1 BOTTLE; Type 0: Not a Combination Product       08/01/2018	# Item (	ode	Package Descrip	tion		-	Marketing End Date			
2       30       Product       07/02/2018         3       NDC:71205-068- 40       40 in 1 BOTTLE; Type 0: Not a Combination Product       07/02/2018         4       NDC:71205-068- 45       45 in 1 BOTTLE; Type 0: Not a Combination Product       08/01/2018         5       NDC:71205-068- 60 in 1 BOTTLE; Type 0: Not a Combination Product       08/01/2018					08/01/2018					
3       40       Product       07/02/2018         4       NDC:71205-068- 45       45 in 1 BOTTLE; Type 0: Not a Combination Product       08/01/2018         5       NDC:71205-068- 60 in 1 BOTTLE; Type 0: Not a Combination 08/01/2018       08/01/2018	2									
4         45         Product         08/01/2018           5         NDC:71205-068-         60 in 1 BOTTLE; Type 0: Not a Combination         08/01/2018	5				07/02/2018					
					08/01/2018					
60 Product 00/01/2018										
6 NDC:71205-068- 90 in 1 BOTTLE; Type 0: Not a Combination Product 08/01/2018										

# **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209312	07/02/2018	

# Labeler - Proficient Rx LP (079196022)

Establishment					
Name	Address	ID/FEI	Business Operations		
Proficient Rx LP		079196022	REPACK(71205-068), RELABEL(71205-068)		

Revised: 4/2022

Proficient Rx LP