HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use DELZICOL safely and effectively. See Full Prescribing Information for DELZICOL.

DELZICOL (mesalamine) delayed-release capsules, for oral use
Initial U.S. Approval: 1987

----------INDICATIONS AND USAGE----------

Delzicol is an aminosalicylate indicated for the treatment of mildly to moderately active ulcerative colitis and for the maintenance of remission of ulcerative colitis (1)

----------DOSAGE AND ADMINISTRATION----------

- For the treatment of mildly to moderately active ulcerative colitis, 800 mg three times daily (2.4 grams total daily dosing) (1, 2)
- For the maintenance of remission of ulcerative colitis, 1.6 g daily, in divided doses (1, 2)
- Swallow whole without cutting, breaking, or chewing (2)
- Dose at least 1 h before or 2 h after a meal (2)
- Two Delzicol 400 mg capsules have not been shown to be bioequivalent to one Asacol HD (mesalamine) delayed-release 800 mg tablet (2)

----------DOSAGE FORMS AND STRENGTHS----------

Delayed-release capsules: 400 mg (3)

----------CONTRAINDICATIONS----------

Patients with known hypersensitivity to salicylates or aminosalicylates or to any of the ingredients of Delzicol capsules (4, 5.3)

----------WARNINGS AND PRECAUTIONS----------

- Renal impairment may occur. Assess renal function at the beginning of treatment and periodically during treatment (5.1)
- Mesalamine-induced acute intolerance syndrome has been reported. Observe patients closely for worsening of these symptoms while on treatment (5.2)
- Use caution when treating patients who are hypersensitive to sulfasalazine (5.3)
- Mesalamine-induced cardiac hypersensitivity reactions (myocarditis and pericarditis) have been reported (5.3)
- Hepatic failure has been reported in patients with pre-existing liver disease. Use caution when treating patients with liver disease (5.4)
- Upper gastrointestinal (GI) tract obstruction may delay onset of action (5.5)

----------ADVERSE REACTIONS----------

The most common adverse reactions (observed in ≥ 5 percent of patients) were abdominal pain, eructation, pain, headache, back pain, diarrhea, rash, dyspepsia, rhinitis, flu syndrome, asthenia, flatulence, vomiting, fever, arthralgia, constipation, and gastrointestinal bleeding (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Warner Chilcott at 1-800-521-8813 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*

---------- ----------DRUG INTERACTIONS----------

- Nephrotoxic agents including NSAIDs: renal reactions have been reported (7.1)
- Azathioprine or 6-mercaptopurine: blood disorders have been reported (7.2)

----------USE IN SPECIFIC POPULATIONS----------

- Renal Impairment: Use Delzicol with caution in patients with a history of renal disease (5.1, 7.1, 8.6)
- Nursing Mothers: Prescribers should carefully evaluate the risk and benefits when mesalamine delayed-release is administered to a nursing mother (8.3)
- Geriatric Patients: Monitor blood cell counts in geriatric patients (8.5)

See 17 for PATIENT COUNSELING INFORMATION.

Revised 02/2013

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Delzicol™ (mesalamine) delayed-release capsules are indicated for the treatment of mildly to moderately active ulcerative colitis and for the maintenance of remission of ulcerative colitis.

2 DOSAGE AND ADMINISTRATION

For the treatment of mildly to moderately active ulcerative colitis, the recommended dose of Delzicol in adults is two 400 mg capsules to be taken three times daily (total daily dose of 2.4 g), for a duration of 6 weeks.

For the maintenance of remission of ulcerative colitis, the recommended dose of Delzicol in adults is 1.6 g daily, in divided doses *[see Clinical Studies* (14.2)*]*.

Swallow whole, do not cut, break, or chew.

Delzicol should be dosed at least 1 hour before a meal or 2 hours after a meal.

Two Delzicol 400 mg capsules have not been shown to be bioequivalent to one Asacol® HD (mesalamine) delayed-release 800 mg tablet.

3 DOSAGE FORMS AND STRENGTHS

Delzicol (mesalamine) delayed-release capsules are red capsules containing 400 mg mesalamine and imprinted with “WC 400mg” in white.

4 CONTRAINDICATIONS

Delzicol is contraindicated in patients with known hypersensitivity to salicylates or aminosalicylates or to any of the ingredients of Delzicol *[see Warnings and Precautions (5.3), Adverse Reactions (6.2), and Description (11)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Renal Impairment

Renal impairment, including minimal change nephropathy, acute and chronic interstitial nephritis, and renal failure, has been reported in patients taking products such as Delzicol that contain mesalamine or are converted to mesalamine.

It is recommended that patients have an evaluation of renal function prior to initiation of Delzicol and periodically while on therapy.

Prescribers should carefully evaluate the risks and benefits when using Delzicol in patients with known renal dysfunction or history of renal disease *[see Drug Interactions (7.1) and Nonclinical Toxicology (13.2)]*.

5.2 Mesalamine-Induced Acute Intolerance Syndrome

Mesalamine has been associated with an acute intolerance syndrome that may be difficult to distinguish from an exacerbation of ulcerative colitis. Although the exact frequency of occurrence has not been determined, it has occurred in 3 percent of controlled clinical trials of mesalamine or sulfasalazine. Symptoms include cramping, abdominal pain, bloody diarrhea, and sometimes fever, headache, and rash. Observe patients closely for worsening of these symptoms while on treatment. If acute intolerance syndrome is suspected, promptly discontinue treatment with Delzicol.

5.3 Hypersensitivity Reactions

Some patients who have experienced a hypersensitivity reaction to sulfasalazine may have a similar reaction to Delzicol or to other compounds that contain or are converted to mesalamine.

Mesalamine-induced cardiac hypersensitivity reactions (myocarditis and pericarditis) have been reported with Delzicol and other mesalamine medications. Caution should be taken in prescribing this medicine to patients with conditions predisposing them to the development of myocarditis or pericarditis.

5.4 Hepatic Failure

There have been reports of hepatic failure in patients with pre-existing liver disease who have been administered mesalamine. Caution should be exercised when administering Delzicol to patients with liver disease.

5.5 Upper GI Tract Obstruction

Organic or functional obstruction in the upper gastrointestinal tract may cause prolonged gastric retention of Delzicol which would delay release of mesalamine in the colon.

6 ADVERSE REACTIONS

The most serious adverse reactions seen in Delzicol clinical trials or with other products that contain or are metabolized to mesalamine are:

•Renal impairment, including renal failure *[see Warnings and Precautions (5.1)]*
•Acute exacerbation of colitis *[see Warnings and Precautions (5.2)]*
•Hypersensitivity reactions *[see Warnings and Precautions (5.3)]*
•Hepatic failure *[see Warnings and Precautions (5.4)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the 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 practice.

The data presented in Sections 6.1 and 6.2 are from clinical trials conducted with mesalamine delayed-release tablets. Delzicol is bioequivalent to these mesalamine delayed-release tablets.

In total, mesalamine delayed-release tablets have been evaluated in 3685 inflammatory bowel disease patients (73 percent of patients with ulcerative colitis) in controlled and open-label trials. Adverse events presented in the following sections may occur regardless of length of therapy and similar events have been reported in short- and long-term studies and in the postmarketing setting.

Treatment of Ulcerative Colitis

Clinical studies supporting mesalamine delayed-release tablets use for the treatment of mildly to moderately active ulcerative colitis included two 6-week, placebo-controlled, randomized, double-blind studies in patients with mildly to moderately active ulcerative colitis. Clinical studies supporting the use of mesalamine delayed-release tablets in the maintenance of remission of ulcerative colitis included a 6-month, randomized, double-blind, placebo-controlled, multi-center study and four active-controlled maintenance trials comparing mesalamine delayed-release with sulfasalazine. Mesalamine delayed-release tablets have been evaluated in 427 patients with ulcerative colitis in these controlled studies.

Treatment of Mildly to Moderately Active Ulcerative Colitis

In two 6-week placebo-controlled clinical studies (Studies 1 and 2) involving 245 patients, 155 of whom were randomized to mesalamine delayed-release tablets *[see Clinical Studies (14.1)]*, five (3.2 percent) of the patients using mesalamine delayed-release tablets discontinued therapy because of adverse reactions as compared to two (2.2 percent) of the placebo patients. The average age of patients in Study 1 was 42 years and 48 percent of patients were male. The average age of patients in Study 2 was 42 years and 59 percent of patients were male. Adverse reactions leading to withdrawal from mesalamine delayed-release tablets included (each in one patient): diarrhea and colitis flare; dizziness, nausea, joint pain, and headache; rash, lethargy and constipation; dry mouth, malaise, lower back discomfort, mild disorientation, mild indigestion and cramping; headache, nausea, aching, vomiting, muscle cramps, a stuffy head, plugged ears, and fever.

Adverse reactions in patients treated with mesalamine delayed-release tablets occurring at a frequency of 2 percent or greater in 6-week, double-blind, placebo-controlled trials (Studies 1 and 2) are listed in Table 1 below.

Table 1

Adverse Reactions Reported in Two Six-Week Placebo-Controlled Trials (Studies 1 and 2) Experienced by at Least 2 Percent of patients in the mesalamine delayed-release tablets Group and at a Rate Greater than Placebo

	Percent of Patients with Adverse Reactions	
	mesalamine delayed-release tablets	Placebo
Event	(n = 152)	(n = 87)
Abdominal pain	18	14
Eructation	16	15
Pain	14	8
Back pain	7	5
Rash	6	3
Dyspepsia	6	1
Arthralgia	5	3
Vomiting	5	2
Constipation	5	1
Chest pain	3	2
Chills	3	2
Peripheral edema	3	2
Myalgia	3	1
Sweating	3	1
Pruritus	3	0
Acne	2	1

Malaise	2	1
Arthritis	2	0

Of these adverse reactions, only rash showed a consistently higher frequency with increasing mesalamine delayed-release tablets dose in these studies.

Maintenance of Remission of Ulcerative Colitis

In a 6-month placebo-controlled maintenance trial involving 264 patients (Study 3) 177 of whom were randomized to mesalamine delayed-release tablets, six (3.4 percent) of the patients using mesalamine delayed-release tablets discontinued therapy because of adverse reactions, as compared to four (4.6 percent) of patients using placebo *[see Clinical Studies (14.2)]*. The average age of patients in Study 3 was 42 years and 55 percent of patients were male. Adverse reactions leading to study withdrawal in patients using mesalamine delayed-release tablets included (each in one patient): anxiety; headache; pruritus; decreased libido; rheumatoid arthritis; and stomatitis and asthenia.

In addition to reactions listed in Table 1, the following adverse reactions occurred in patients using mesalamine delayed-release tablets at a frequency of 2 percent or greater in Study 3: abdominal enlargement, gastroenteritis, gastrointestinal hemorrhage, infection, joint disorder, migraine, nervousness, paresthesia, rectal disorder, rectal hemorrhage, stool abnormalities, tenesmus, urinary frequency, vasodilation, and vision abnormalities.

In 3342 patients in uncontrolled clinical studies, the following adverse reactions occurred at a frequency of 5 percent or greater and appeared to increase in frequency with increasing dose: asthenia, fever, flu syndrome, pain, abdominal pain, back pain, flatulence, gastrointestinal bleeding, arthralgia, and rhinitis.

6.2 Postmarketing Experience

In addition to the adverse reactions reported above in clinical trials involving mesalamine delayed-release tablets, the adverse reactions listed below have been identified during post-approval use of mesalamine delayed-release tablets and other mesalamine-containing products. 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.

Body as a Whole: Neck pain, facial edema, edema, lupus-like syndrome, drug fever.

Cardiovascular: Pericarditis, myocarditis.

Gastrointestinal: Anorexia, pancreatitis, gastritis, increased appetite, cholecystitis, dry mouth, oral ulcers, perforated peptic ulcer bloody diarrhea.

Hematologic: Agranulocytosis aplastic anemia, thrombocytopenia, eosinophilia, leukopenia, anemia, lymphadenopathy.

Musculoskeletal: Gout.

Nervous: Depression, somnolence, emotional lability, hyperesthesia, vertigo, confusion, tremor, peripheral neuropathy, transverse myelitis, Guillain-Barré syndrome.

Renal: Renal Failure, interstitial nephritis, minimal change nephropathy *[see Warnings and Precautions (5.1)]*.

Respiratory/Pulmonary: Eosinophilic pneumonia, interstitial pneumonitis, asthma exacerbation, pleuritis.

Skin: Alopecia, psoriasis, pyoderma gangrenosus, dry skin, erythema nodosum, urticaria.

Special Senses: Eye pain, taste perversion, blurred vision, tinnitus.

Urogenital: Dysuria, urinary urgency, hematuria, epididymitis, menorrhagia, reversible oligospermia.

Laboratory Abnormalities: Elevated AST (SGOT) or ALT (SGPT), elevated alkaline phosphatase, elevated GGT, elevated LDH, elevated bilirubin, elevated serum creatinine and BUN.

7 DRUG INTERACTIONS

No formal drug interaction studies have been performed using Delzicol with other drugs. However, the following interactions between mesalamine medications and other drugs have been reported.

7.1 Nephrotoxic Agents, Including Non-Steroidal Anti-Inflammatory Drugs

The concurrent use of mesalamine with known nephrotoxic agents, including nonsteroidal anti-inflammatory drugs (NSAIDs) may increase the risk of renal reactions.

7.2 Azathioprine or 6-mercaptopurine

The concurrent use of mesalamine with azathioprine or 6-mercaptopurine may increase the risk for blood disorders.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary
Pregnancy Category B: There are no adequate and well controlled studies of Delzicol use in pregnant women. Limited published human data on mesalamine show no increase in the overall rate of congenital malformations. Some data show an increased rate of preterm birth, stillbirth, and low birth weight; however, these adverse pregnancy outcomes are also associated with active inflammatory bowel disease. Animal reproduction studies of mesalamine found no evidence of fetal harm.

Human Data
Mesalamine crosses the placenta. In prospective and retrospective studies of over 600 women exposed to mesalamine during pregnancy, the observed rate of congenital malformations was not increased above the background rate in the general population. Some data show an increased rate of preterm birth, stillbirth, and low birth weight, but it is unclear whether this was due to underlying maternal disease, drug exposure, or both, as active inflammatory bowel disease is also associated with adverse pregnancy outcomes.

Animal data
Reproduction studies with mesalamine were performed during organogenesis in rats and rabbits at oral doses up to 480 mg/kg/day. There was no evidence of impaired fertility or harm to the fetus. These mesalamine doses were about 1.9 times (rat) and 3.9 times (rabbit) the recommended human dose, based on body surface area.

8.3 Nursing Mothers

Mesalamine and its N-acetyl metabolite are excreted into human milk. In published lactation studies, maternal mesalamine doses from various oral and rectal formulations and products ranged from 500 mg to 3 g daily. The concentration of mesalamine in milk ranged from non-detectable to 0.11 mg/L. The concentration of the N-acetyl-5-aminosalicylic acid metabolite ranged from 5 to 18.1 mg/L. Based on these concentrations, estimated infant daily doses for an exclusively breastfed infant are 0 to 0.017 mg/kg/day of mesalamine and 0.75 to 2.72 mg/kg/day of N-acetyl-5-aminosalicylic acid. Caution should be exercised when Delzicol is administered to a nursing woman.

8.4 Pediatric Use

Safety and effectiveness of Delzicol in pediatric patients have not been established.

8.5 Geriatric Use

Clinical studies of mesalamine delayed-release tablets did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently than younger subjects. Other reported clinical experience has not identified differences in response between the elderly and younger patients. In general, the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy in elderly patients should be considered when prescribing Delzicol. Reports from uncontrolled clinical studies and postmarketing reporting systems suggest a higher incidence of blood dyscrasias, that is, agranulocytosis, neutropenia, pancytopenia, in subjects receiving mesalamine delayed-release tablets who are 65 years or older. Caution should be taken to closely monitor blood cell counts during treatment with Delzicol.

8.6 Renal Impairment

Mesalamine is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken when prescribing this drug therapy. It is recommended that all patients have an evaluation of renal function prior to initiation of Delzicol therapy and periodically while on Delzicol therapy *[see Warnings and Precautions (5.1)]*.

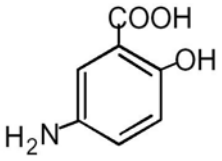
10 OVERDOSAGE

There is no specific antidote for mesalamine overdose and treatment for suspected acute severe toxicity with Delzicol should be symptomatic and supportive. This may include prevention of further gastrointestinal tract absorption, correction of fluid electrolyte imbalance, and maintaining adequate renal function. Delzicol is a pH dependent delayed-release product and this factor should be considered when treating a suspected overdose.

11 DESCRIPTION

Each Delzicol (mesalamine) delayed-release capsule for oral administration contains 400 mg of mesalamine, an aminosalicylate. Mesalamine is a non-steroidal anti-inflammatory agent. Delzicol (mesalamine) delayed-release capsules contain acrylic based resin, Eudragit S (methacrylic acid copolymer type B, NF), which dissolves at pH 7 or greater and releases mesalamine in the terminal ileum and beyond for topical anti-inflammatory action in the colon. Mesalamine (also referred to as 5-

aminosalicylic acid or 5-ASA) has the chemical name 5-amino-2-hydroxybenzoic acid. Its structural formula is:



Molecular Weight: 153.1
Molecular Formula: $C_7H_7NO_3$

Inactive Ingredients: Each capsule contains colloidal silicon dioxide, dibutyl sebacate, ferric oxide red, ferric oxide yellow, lactose monohydrate, magnesium stearate, methacrylic acid copolymer type B (Eudragit S), polyethylene glycol, povidone, sodium starch glycolate, talc and hydroxypropyl methylcellulose (HPMC).

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The mechanism of action of mesalamine is unknown, but appears to be topical rather than systemic. Mucosal production of arachidonic acid metabolites, both through the cyclooxygenase pathways, that is, prostanoids, and through the lipoxygenase pathways, that is, leukotrienes and hydroxyeicosatetraenoic acids, is increased in patients with chronic ulcerative colitis, and it is possible that mesalamine diminishes inflammation by blocking cyclooxygenase and inhibiting prostaglandin production in the colon.

12.3 Pharmacokinetics

Absorption
Approximately 28 percent of mesalamine in mesalamine delayed-release formulations is absorbed after oral ingestion. The T_{max} for mesalamine and its metabolite, is usually delayed, reflecting the delayed-release, and ranges from 4 to 16 hours.

The effect of food on the absorption of mesalamine from Delzicol has not been evaluated.

Metabolism
The absorbed mesalamine is rapidly acetylated in the gut mucosal wall and by the liver to N-acetyl-5-aminosalicylic acid.

Excretion
Absorbed mesalamine is excreted mainly by the kidney as N-acetyl-5-aminosalicylic acid. Unabsorbed mesalamine is excreted in feces.

After intravenous administration, the elimination half-life of mesalamine is reported to be approximately 40 minutes. After oral dosing, the terminal t1/2 values for mesalamine and N-acetyl-5-aminosalicylic acid are usually about 12 hours, but are variable, ranging from 2 to 15 hours. There is a large inter-subject and intra-subject variability in the plasma concentrations of mesalamine and N-acetyl-5-aminosalicylic acid and in their elimination half-lives following administration of Delzicol.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis
Mesalamine was not carcinogenic at dietary doses of up to 480 mg/kg/day in rats and 2000 mg/kg/day in mice, which are about 2.9 and 6.1 times the maximum recommended maintenance dose of Delzicol of 1.6 g/day or 26.7 mg/kg/day, based on 60 kg body weight, respectively, based on body surface area.

Mutagenesis
Mesalamine was negative in the Ames assay for mutagenesis, negative for induction of sister chromatid exchanges (SCE) and chromosomal aberrations in Chinese hamster ovary cells *in vitro*, and negative for induction of micronuclei (MN) in mouse bone marrow polychromatic erythrocytes.

Impairment of Fertility
Mesalamine, at oral doses up to 480 mg/kg/day (about 1.9 times the recommended human treatment dose on a body surface area basis), was found to have no effect on fertility or reproductive performance of male and female rats.

13.2 Animal Toxicology and/or Pharmacology

In animal studies (rats, mice, dogs), the kidney was the principal organ for toxicity. (In the following, comparisons of animal dosing to recommended human dosing are based on body surface area and a 2.4 g/day dose for a 60 kg person.)

Mesalamine causes renal papillary necrosis in rats at single doses of approximately 750 mg/kg to 1000 mg/kg (approximately 3 to 4 times the recommended human dose based on body surface area). Doses of 170 and 360 mg/kg/day (about 0.7 and 1.5 times the recommended human dose based on body surface area) given to rats for six months produced papillary necrosis, papillary edema, tubular degeneration, tubular mineralization, and urothelial hyperplasia.

In mice, oral doses of 4000 mg/kg/day mesalamine (approximately 8 times the recommended human dose based on body surface area) for three months produced tubular nephrosis, multifocal/diffuse tubulo-interstitial inflammation, and multifocal/diffuse papillary necrosis.

In dogs, single doses of 6000 mg (approximately 8 times the recommended human dose based on body surface area) of delayed-release mesalamine tablets resulted in renal papillary necrosis but were not fatal. Renal changes have occurred in dogs given chronic administration of mesalamine at doses of 80 mg/kg/day (1.1 times the recommended human dose based on body surface area).

14 CLINICAL STUDIES

The data presented in Section 14 are from clinical trials conducted with mesalamine delayed-release tablets. Delzicol is bioequivalent to these mesalamine delayed-release tablets.

14.1 Mildly to Moderately Active Ulcerative Colitis

Two placebo-controlled studies have demonstrated the efficacy of mesalamine delayed-release tablets in patients with mildly to moderately active ulcerative colitis. In one randomized, double-blind, multi-center trial of 158 patients, mesalamine delayed-release doses of 1.6 g/day and 2.4 g/day for 6 weeks were compared to placebo. The scoring system for determination of treatment efficacy included assessment of stool frequency, rectal bleeding, sigmoidoscopic findings, patient's functional assessment,

and physician global assessment. At the dose of 2.4 g/day, 21 of 43 (49 percent) patients using mesalamine delayed-release tablets showed an improvement in sigmoidoscopic appearance of the bowel compared to 12 of 44 (27 percent) patients using placebo ($p = 0.048$). In addition, significantly more patients in mesalamine delayed-release tablets 2.4 g/day group showed improvement in rectal bleeding and stool frequency. The 1.6 g/day dose did not produce consistent evidence of effectiveness.

In a second randomized, double-blind, placebo-controlled clinical trial of 6 weeks duration in 87 patients, mesalamine delayed-release tablets, at a dose of 4.8 g/day, for 6 weeks, resulted in sigmoidoscopic improvement in 28 of 38 (74 percent) patients compared to 10 of 38 (26 percent) placebo patients ($p < 0.001$). Also, more patients in the mesalamine delayed-release tablets 4.8 g/day group showed improvement in overall symptoms.

14.2 Maintenance of Remission of Ulcerative Colitis

A 6-month, randomized, double-blind, placebo-controlled, multi-center study involved 264 patients treated with mesalamine delayed-release tablets 0.8 g/day (n = 90), 1.6 g/day (n = 87), or placebo (n = 87). In the 0.8g/day arm, patients were dosed twice daily; in the 1.6 g/day arm, patients were dosed four times daily. The proportion of patients treated with 0.8 g/day who maintained endoscopic remission was not statistically significant compared to placebo. The proportion of patients using mesalamine delayed-release tablets 1.6 g/day who maintained endoscopic remission of ulcerative colitis was in 61 of 87 (70.1 percent) compared with 42 of 87 (48.3 percent) of placebo patients ($p = 0.005$).

A pooled efficacy analysis of 4 maintenance trials compared mesalamine delayed-release tablets, at doses of 0.8 g/day to 2.8 g/day, in divided doses ranging from twice daily to four times per day, with sulfasalazine, at doses of 2 g/day to 4 g/day. Treatment success was seen in 59 of 98 (59 percent) patients using mesalamine delayed-release tablets and 70 of 102 (69 percent) of patients using sulfasalazine, a non-significant difference.

16 HOW SUPPLIED/STORAGE AND HANDLING

Delzicol (mesalamine) delayed-release capsules are available as red capsules containing 400 mg mesalamine and imprinted with “WC 400mg” in white.

NDC 0430-0753-27 Bottle of 180 capsules

Store at controlled room temperature 20° to 25° C (68° to 77° F); excursions are permitted 15° to 30° C (59° to 86° F). [See USP Controlled Room Temperature]

17 PATIENT COUNSELING INFORMATION

- Instruct patients to swallow the Delzicol whole, taking care not to break, cut, or chew the capsules, because the coating is an important part of the delayed-release formulation.
- Instruct patients to take Delzicol at least one hour before a meal or two hours after a meal.
- Inform patients that if they are switching from a previous oral mesalamine therapy to Delzicol they should discontinue their previous oral mesalamine therapy and follow the dosing instructions for Delzicol.
- Inform patients that intact, partially intact, and/or capsule shells have been reported in the stool. Instruct patients to contact their physician if this occurs repeatedly.

- Instruct patients to protect Delzicol from moisture. Instruct patients to close the container tightly and to leave any desiccant pouches present in the bottle along with the capsules.

Manufactured by:
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D-64331 Weiterstadt
Germany

Marketed by:
Warner Chilcott (US), LLC
Rockaway, NJ 07866

Under license from Medeva Pharma Suisse AG (registered trademark owner).

U.S. Patent Nos. 5,541,170 and 5,541,171

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