Mesalamine is used to treat ulcerative colitis, a type of bowel disease. It does not cure ulcerative colitis, but it may decrease symptoms such as stomach pain, diarrhea, and rectal bleeding caused by irritation/swelling of the colon/rectum.

Active Pharmaceuticals Ingredients Manufacturers



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Taj Pharmaceuticals Ltd. Mesalazine CAS No. : 89-57-6

Molecular Formula C7H7NO3 Molecular Weight 153.14 CAS Registry Number 89-57-6 ATC code A07EC02 PubChem 4075 DrugBank APRD01098

Chemical data

Formula C7H7NO3 Mol. mass 153.135 g/mol SMILES eMolecules & PubChem

Pharmacokinetic data

Bioavailability orally: 20-30% absorbed rectally: 10-35% Metabolism Rapidly & extensively metabolised intestinal mucosal wall and the liver. Half life 5 hours after initial dose. At steady state 7 hours

DOSAGE

Take this medication exactly as it was prescribed for you. Do not take the medication in larger amounts, or take it for longer than recommended by your doctor. Follow the directions on your prescription label. Take mesalamine with a full glass of water.

Mesalamine can usually be taken with or without food. Follow your doctor's instructions. Mesalamine extended-release capsules(Lialda) should be taken with a meal. Do not crush, break, or chew a mesalamine tablet or capsule. Swallow the pill whole.

The extended-release capsule is specially formulated to release the medicine after it has passed through your stomach into your intestines. Breaking the pill may cause the drug to be released too early in the digestive tract.

The enteric-coated tablet has a special coating to protect your stomach. Breaking the pill could damage this coating.

How to use mesalazine suppositories

1. You should go to the toilet to empty your bowels and bladder (if necessary) before inserting the suppository.

If the suppository is too soft, it may be cooled in the refrigerator or under cold running water before unwrapping.
Remove the wrapping and moisten the suppository with water. Lie on your left side (if you are right handed) and draw your knees up towards your chest, with the right leg drawn up more than the left.

4. Using your first finger or middle finger (whichever you find easiest), gently push the suppository into the rectum (back passage), pointed end first.

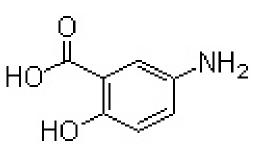
5. The suppository should be inserted as far as possible, pushing the end of the suppository sideways to ensure contact with the wall of the bowel.

6. Lower your legs to a comfortable position to help you to hold the suppository in place.



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Taj Pharmaceuticals Ltd.



CAS NO- 89-57-6

How to use mesalazine liquid enema

1. Lie on your left side (if you are right handed) and draw your knees up towards your chest, with the right leg drawn up more than the left.

- 2. Remove the top from the enema.
- 3. Insert the tube into the rectum (back passage) as far as the mark on the nozzle.
- 4. Empty the contents completely by squeezing the tube between the index finger and thumb.
- 5. When the tube is empty, remove it from the rectum and throw away.

6. After using the dose, lower your legs to a comfortable position to help hold the medicine in place.

How to use mesalazine foam enema

1. Shake the canister vigorously to mix the contents.

2. If you are using this preparation for the first time you will need to remove the safety tag from just underneath the dome (on the top of the container).

- 3. Push the applicator firmly on to the nozzle of the canister.
- 4. Standing up, place one foot on to a firm surface, such as a chair.
- 5. Hold the canister upside down (with the dome facing down) in the palm of your hand.
- 6. Insert the applicator in to the rectum (back passage) as far as it will go comfortably.

7. Push the dome once and release. If you have been instructed to administer two doses, press the dome again and release. The foam is not administered until the dome is released.

- 8. Remove applicator from your rectum.
- 9. Remove the applicator from the canister, place in one of the plastic bags provided and dispose of in a bin.

SIDE EFFECTS

Diarrhea, headache, nausea, vomiting, or loss of appetite may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: rash, itching, swelling, severe dizziness, trouble breathing. PRECAUTIONS: Before taking this medication, tell your doctor or pharmacist if you are allergic to it; or to other medications that are broken down into mesalamine (e.g., sulfasalazine, olsalazine); or to other salicylates (e.g., aspirin); or if you have any other allergies.

PRECAUTIONS

General

Caution should be exercised if Mesalazine is administered to patients with impaired hepatic function. Mesalamine has been associated with an acute intolerance syndrome that may be difficult to distinguish from a flare of inflammatory bowel disease. Although the exact frequency of occurrence cannot be ascertained, it has occurred in 3% of patients in controlled clinical trials of mesalamine or sulfasalazine. Symptoms include cramping, acute abdominal pain and bloody diarrhea, sometimes fever, headache, and rash. If acute intolerance syndrome is suspected, prompt withdrawal is required. If a rechallenge is performed later in order to validate the hypersensitivity, it should be carried out under close medical supervision at reduced dose and only if clearly needed.

Renal

Caution should be exercised if Mesalazine is administered to patients with impaired renal function. Single reports of nephrotic syndrome and interstitial nephritis associated with mesalamine therapy have been described in the foreign literature. There have been rare reports of interstitial nephritis in patients receiving Mesalazine . In animal studies, a 13-week oral toxicity study in mice and 13-week and 52-week oral toxicity studies in rats and cynomolgus monkeys have shown the kidney to be the major target organ of mesalamine toxicity.



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Oral daily doses of 2400 mg/kg in mice and 1150 mg/kg in rats produced renal lesions including granular and hyaline casts, tubular degeneration, tubular dilation, renal infarct, papillary necrosis, tubular necrosis, and interstitial nephritis. In cynomolgus monkeys, oral daily doses of 250 mg/kg or higher produced nephrosis, papillary edema, and interstitial fibrosis. Patients with preexisting renal disease, increased BUN or serum creatinine, or proteinuria should be carefully monitored, especially during the initial phase of treatment. Mesalamine-induced nephrotoxicity should be suspected in patients developing renal dysfunction during treatment.

Pediatric Use

Safety and efficacy of Mesalazine in pediatric patients have not been established.

DRUG DESCRIPTION

Mesalazine also known as Mesalamine

is an anti-inflammatory drug used to treat inflammation of the digestive tract ulcerative colitis and mild to moderate Crohn's disease. Mesalazine is a bowel-specific aminosalicylate drug that acts locally in the gut and has its predominant actions there, thereby having few systemic side effects.

As a derivative of salicylic acid, 5-ASA is also an antioxidant that traps free radicals, which are potentially damaging by-products of metabolism.

Not used in Allergy to salicylates

Severe kidney impairment

Active peptic ulcer

Bleeding tendencies

Used for Treatment and prevention of ulcerative colitis

Mesalazineis a medicine which is used in active ulcerative colitis, active ulcerative proctitis, maintaining remission from Crohn's ileo-colitis, maintaining remission from ulcerative colitis and maintaining remission from ulcerative proctitis.Mesalamine affects a substance in the body that causes inflammation, tissue damage, and diarrhea.

Mesalamine is used to treat ulcerative colitis, proctitis, and proctosigmoiditis. Mesalamine is also used to prevent the symptoms of ulcerative colitis from recurring.



PHARMACEUTICALS

ACTIVE PHARMACEUTICAL INGREDIENTS

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to themanufacture of the substances. For any (Control Substance) products Import and Export *** subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

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