



Drugs and Supplements

Mesalamine (Oral Route)

Description and Brand Names

Drug information provided by: [Micromedex](#)

US Brand Name

Apriso

Asacol HD

Delzicol

Lialda

Canadian Brand Name

Pentasa

Asacol 800

Descriptions

Mesalamine is used to treat and prevent ulcerative colitis (an inflammatory bowel disease). It works inside the intestine (bowel) to reduce inflammation and other symptoms of the disease.

This medicine is available only with your doctor's prescription.

Once a medicine has been approved for marketing for a certain use, experience may show that it is also useful for other medical problems. Although this use is not included in product labeling, mesalamine is used in certain patients with the following medical conditions:

- Mild or moderate Crohn disease—Treatment and prevention of flare-ups.

This product is available in the following dosage forms:

- Capsule, Delayed Release
- Tablet, Delayed Release
- Tablet, Enteric Coated
- Capsule, Extended Release
- Tablet

Before Using

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For this medicine, the following should be considered:

Allergies

Tell your doctor if you have ever had any unusual or allergic reaction to this medicine or any other medicines. Also tell your health care professional if you have any other types of allergies, such as to foods, dyes, preservatives, or animals. For non-prescription products, read the label or package ingredients carefully.

Pediatric

Appropriate studies performed to date have not demonstrated pediatric-specific problems that would limit the usefulness of Delzicol® for the treatment of ulcerative colitis in children 5 years and older. Safety and efficacy have not been established in children younger than 5 years. The safety and efficacy of Delzicol® have not been established for the prevention of ulcerative colitis in children.

Appropriate studies have not been performed on the relationship of age to the effects of Apriso™, Asacol® HD, Lialda®, or Pentasa® in the pediatric population. Safety and efficacy have not been established.

Geriatric

Appropriate studies performed to date have not demonstrated geriatric-specific problems that would limit the usefulness of mesalamine in the elderly. However, elderly patients are more likely to have blood problems and age-related kidney disease, which may require caution and an adjustment in the dose for patients receiving mesalamine.

Pregnancy

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	Pregnancy Category	Explanation
All Trimesters	B	Animal studies have revealed no evidence of harm to the fetus, however, there are no adequate studies in pregnant women OR animal studies have shown an adverse effect, but adequate studies in pregnant women have failed to demonstrate a risk to the fetus.

Breastfeeding

There are no adequate studies in women for determining infant risk when using this medication during breastfeeding. Weigh the potential benefits against the potential risks before taking this medication while breastfeeding.

Drug Interactions

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. When you are taking this medicine, it is especially important that your healthcare professional know if you are taking any of the medicines listed below. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Using this medicine with any of the following medicines is usually not recommended, but may be required in some cases. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

- Mercaptopurine
- Varicella Virus Vaccine

Using this medicine with any of the following medicines may cause an increased risk of certain side effects, but using both drugs may be the best treatment for you. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

- Tamarind
- Warfarin

Other Interactions

Certain medicines should not be used at or around the time of eating food or eating certain types of food since interactions may occur. Using alcohol or tobacco with certain medicines may also cause interactions to occur. Discuss with your healthcare professional the use of your medicine with food, alcohol, or tobacco.

Other Medical Problems

The presence of other medical problems may affect the use of this medicine. Make sure you tell your doctor if you have any other medical problems, especially:

- Allergy to sulfasalazine (Azulfidine®)—May cause side effects to become worse.
- Kidney disease—Use with caution. The effects may be increased because of slower removal of the medicine from the body.
- Liver disease—Use with caution. May make this condition worse.
- Phenylketonuria (PKU)—The Apriso™ capsules contain aspartame, which may require caution in patients with PKU.

Proper Use

Take this medicine exactly as directed by your doctor. Do not take more of it, do not take it more often, and do not take it for a longer time than your doctor ordered. Do not stop taking this medicine without checking with your doctor first.

Keep taking this medicine for the full time of treatment, even if you begin to feel better after a few days. Do not miss any doses.

You should take the Lialda® tablets with food. All other brands of capsules and tablets can be taken with or without food.

Swallow the capsule or tablet whole. Do not open, break, crush, or chew it before swallowing.

If you have trouble swallowing the Delzicol® capsule, carefully open the capsule and take out the 4 tablets. Swallow the tablets whole and make sure all 4 are taken at the same time as one dose. Do not cut, break, crush, or chew them.

The contents of the Pentasa® capsule may be sprinkled on applesauce or yogurt if needed. The mixture must be swallowed right away without chewing.

If you are taking the delayed-release capsule, extended-release capsule, or delayed-release tablet, part of the capsule or tablet may pass into your stool after your body has absorbed the medicine. Contact your doctor if this happens more often than 1 or 2 times.

Dosing

The dose of this medicine will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

- For the treatment of ulcerative colitis:
 - For long-acting oral dosage form (delayed-release capsules):
 - Adults—800 milligrams (mg) 3 times a day.
 - Children 5 years and older—Dose is based on body weight and must be determined by your doctor. The dose is usually not more than 2400 mg per day, divided in 2 doses.
 - Children younger than 5 years—Use and dose must be determined by your doctor.
 - For long-acting oral dosage form (delayed-release tablets):
 - Adults—
 - For Asacol® HD: 1600 milligrams (mg) 3 times a day for 6 weeks.
 - For Lialda®: 2.4 to 4.8 grams once a day as a single dose.
 - Children—Use and dose must be determined by your doctor.
 - For long-acting oral dosage form (extended-release capsules):
 - Adults—
 - For Apriso™: 1.5 grams once a day as a single dose in the morning.
 - For Pentasa®: 1 gram 4 times a day.
 - Children—Use and dose must be determined by your doctor.
- For prevention of ulcerative colitis:
 - For long-acting oral dosage form (delayed-release capsules):
 - Adults—1600 milligrams (mg) per day, taken in divided doses.
 - Children—Use and dose must be determined by your doctor.
 - For long-acting oral dosage form (delayed-release tablets):
 - Adults—2.4 grams once a day as a single dose.

- Children—Use and dose must be determined by your doctor.

Missed Dose

If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

Storage

Keep out of the reach of children.

Do not keep outdated medicine or medicine no longer needed.

Ask your healthcare professional how you should dispose of any medicine you do not use.

Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light. Keep from freezing.

Store the delayed-release capsules and delayed-release tablets in a tightly-closed container to protect them from moisture.

Precautions

It is important that your doctor check your progress at regular visits. This will allow your doctor to see if the medicine is working properly and to decide if you should continue to take it. Blood or urine tests may be needed to check for unwanted effects.

Check with your doctor right away if you have abdominal or stomach pain, bloody diarrhea, cramps, fever, headache, or a rash while you are using this medicine. These may be symptoms of a condition called mesalamine-induced acute intolerance syndrome.

Call your doctor right away if you have difficult breathing or swallowing, a fast heartbeat, itching, rash, or skin redness, or swelling of the face, throat, or tongue. These may be symptoms of an allergic reaction to this medicine.

Check with your doctor right away if you have pain or tenderness in the upper stomach, pale stools, dark urine, loss of appetite, nausea, vomiting, or yellow eyes or skin. These could be symptoms of a serious liver problem.

Do not take antacids (eg, Amphojel®, Maalox®, Mylanta®, Tums®) while you are taking the Apriso™ capsules. Using these medicines together may change the amount of medicine that is released in the body.

Do not take other medicines unless they have been discussed with your doctor. This includes prescription or nonprescription (over-the-counter [OTC]) medicines and herbal or vitamin supplements.

Side Effects

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur:

More common

- Abdominal or stomach pain (severe)
- bloody diarrhea
- rectal bleeding

Less common

- Abdominal or stomach cramps (severe)
- blurred vision
- dizziness
- fever
- full or bloated feeling
- headache (severe)
- nervousness
- pounding in the ears
- pressure in the stomach
- skin rash and itching
- slow or fast heartbeat
- swelling of the abdominal or stomach area
- unusual tiredness or weakness

Rare

- Anxiety
- back pain (severe)
- blue or pale skin
- chest pain, possibly moving to the left arm, neck, or shoulder
- chills

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- nausea or vomiting
- yellow eyes or skin

Some side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects. Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:

More common

- Abdominal or stomach cramps or pain (mild)
- diarrhea (mild)
- headache (mild)
- runny or stuffy nose
- sneezing

Less common

- Acid or sour stomach
- acne
- back or joint pain
- belching
- difficulty with moving
- excess air or gas in the stomach or intestines
- hair loss or thinning of the hair
- heartburn
- indigestion
- loss of appetite
- muscle pain or stiffness
- passing gas
- stomach discomfort or upset

Other side effects not listed may also occur in some patients. If you notice any other effects, check with your healthcare professional.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

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