



Drugs and Supplements

Mesalamine (Rectal Route)

Description and Brand Names

Drug information provided by: [Micromedex](#)

US Brand Name

Canasa

Rowasa

sfRowasa

Canadian Brand Name

Mesasal

Pentasa

Salofalk

Descriptions

Mesalamine is used to treat an inflammatory bowel disease, such as ulcerative colitis. Mesalamine suppositories are used to treat mild to moderate active ulcerative proctitis (inflammation of the rectum). It works inside the intestines (bowels) to reduce the 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 condition:

- Ulcerative colitis, history of—prevent it from occurring again.

This product is available in the following dosage forms:

- Suppository
- Enema

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 have not been performed on the relationship of age to the effects of mesalamine 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 (eg, neutropenia, pancytopenia) and age-related kidney disease, which may require caution and an adjustment in the dose for patients receiving mesalamine.

Pregnancy

	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 salicylates (eg, aspirin) or

- Allergy to saturated vegetable fat—Should not be used in patients with these conditions.
- Allergy to sulfasalazine (Azulfidine®) or
- Kidney disease, or history of or
- Liver disease or
- Myocarditis (heart disease), history of or
- Pericarditis (heart disease), history of or
- Stomach blockage—Use with caution. May make these conditions worse.

Proper Use

Use this medicine exactly as directed by your doctor. Do not use it more often, and do not use it for a longer time than your doctor ordered.

This medicine comes with a patient information insert. Read and follow the instructions carefully. Ask your doctor if you have any questions.

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

For best results, empty your bowel just before using the rectal enema or suppository.

If you are using the enema:

- This medicine usually comes with patient directions. Read them carefully before using this medicine.
- Remove the bottles from the protective foil pouch, being careful not to squeeze or puncture them. The enema is an off-white to tan color. Contents of the enemas removed from the foil pouch may darken with time. Slight darkening will not affect the potency of the contents. However, enemas with dark brown contents should be discarded.
- Shake the bottle well to make sure that the medication is thoroughly mixed. Remove the protective cover from the applicator tip. Hold bottle at the neck so that no medicine spills out.
- Lie on your left side with your left leg straight and your right knee bent in front of you for balance. You can also lie in the knee-chest position, on your knees with your chest touching the bed.
- Gently insert the rectal tip of the enema applicator pointed slightly toward your naval to prevent damage to the rectal wall. Tilt the nozzle slightly toward the back and

squeeze slowly to cause the enema to flow into your rectum. Steady pressure will discharge most of the medicine. After administering, withdraw and discard the bottle.

- Remain in position for at least 30 minutes to allow the medicine to distribute thoroughly. Retain the medicine all night if possible.

If you are using the suppository:

- Never take rectal suppositories by mouth.
- Remove one suppository from the strip of suppositories. Hold suppository upright and carefully remove the foil wrapper.
- Before inserting a suppository, go to the bathroom and empty your bladder and, if possible, have a bowel movement.
- This medicine will stain any surface it touches (eg, clothing, bedsheets, floors, countertops, etc.). To protect your clothing, consider wearing a sanitary napkin or adult undergarment such as Depend®. Protect your sheets by placing a waterproof pad on your bed. These pads, often called Chux® pads or underpads, are available from a medical supply store.
- Wash your hands with soap and water before and after using this medicine. Remove the foil or wrapper from the suppository before inserting it.
- Do not keep the suppository in your hand too long or it may begin to melt.
- To make the suppository easier to insert, you may use a lubricating gel such as K-Y® Jelly, but do not use petroleum jelly (Vaseline®).
- Insert suppository (pointed end first) completely into rectum with gentle pressure.
- The medicine needs to remain in your body for 1 to 3 hours or longer, depending on your doctor's advice. Try not to use the bathroom for at least that length of time after inserting the suppository.

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 ulcerative colitis or proctitis:
 - For rectal dosage form (enema):

- Adults—4 grams (1 unit) every night for 3 to 6 weeks.
- Children—Use and dose must be determined by your doctor.
- For rectal dosage form (suppository):
 - Adults—1000 milligrams (mg) inserted into your rectum once a day at bedtime for 3 to 6 weeks.
 - 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.

You may store the suppositories in the refrigerator, but do not freeze them.

Store the enema at room temperature, away from heat, moisture, and direct light. Keep from freezing.

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 use it. Urine or blood tests may be needed to check for unwanted effects.

Check with your doctor right away if you have bloody urine, decreased amount of urine, lower back or side pain, swelling of the face, fingers, or lower legs, or unusual tiredness or weakness. These could be symptoms of kidney problems.

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.

Tell your doctor right away if you experience chest pain or trouble breathing.

Check with your doctor if you notice rectal bleeding, blistering, pain, burning, itching, or other sign of irritation not present before you started using this medicine.

Mesalamine may stain clothing, fabrics, flooring, painted surfaces, marble, granite, vinyl, enamel, or other surfaces it touches.

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:

Less common or rare

- Abdominal or stomach cramps or pain (severe)
- anxiety
- back pain (severe)
- bloody, black, or tarry stools
- blue or pale skin
- bright red blood in the stool
- chest pain, possibly moving to the left arm, neck, or shoulder
- chills
- diarrhea (severe)
- fast heartbeat
- fever
- headache (severe)
- nausea or vomiting
- skin rash
- stomach cramps, tenderness, or pain
- swelling of the stomach
- unusual tiredness or weakness
- watery or bloody diarrhea
- yellow eyes or skin

Incidence not known

- Blood in the urine
- change in the frequency of urination or amount of urine
- cough
- dark-colored urine
- difficulty with breathing
- drowsiness
- general feeling of tiredness or weakness
- high fever
- increased thirst
- light-colored stools
- loss of appetite
- lower back or side pain
- painful or difficult urination
- pale skin
- sore throat
- sores, ulcers, or white spots on lips or in mouth
- stomach pain, continuing
- swelling of the feet or lower legs
- swollen glands
- troubled breathing
- unexplained or unusual bleeding or bruising
- weakness

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)
- bloated or full feeling
- excess air or gas in stomach or intestines

- gas or flatulence
- headache (mild)
- passing gas

Less common

- Acne
- diarrhea
- dizziness
- leg or joint pain
- loss of hair
- rectal pain or irritation

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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