

Mesalamine suppositories, for rectal use (me s al' a meen)

Patient Information

What are mesalamine suppositories?

Mesalamine suppositories are a prescription medicine used to treat adults with active ulcerative proctitis (ulcerative rectal colitis).

It is not known if mesalamine suppositories are safe and effective in children.

Do not use mesalamine suppositories if you are:

- allergic to medicines that contain salicylates, including aspirin.
- allergic to mesalamine or any of the ingredients in mesalamine suppositories. See the end of this Patient Information leaflet for a complete list of ingredients in mesalamine suppositories.

Ask your doctor if you are not sure if your medicine is listed above.

Before using mesalamine suppositories, tell your doctor if you:

- have a history of allergic reaction to the medicine sulfasalazine (Azulfidine).
- have kidney problems.
- have ever had inflammation of the sac around your heart (pericarditis).
- have liver problems.
- have any other medical conditions.
- are pregnant or plan to become pregnant. It is not known if mesalamine can harm your unborn baby.
- are breastfeeding or plan to breastfeed. Mesalamine can pass into your breast milk. Talk to your doctor about the best way to feed your baby if you use mesalamine suppositories.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

Using mesalamine suppositories with certain other medicines may affect each other. Using mesalamine suppositories with other medicines can cause serious side effects.

Especially tell your doctor if you take nonsteroidal anti-inflammatory drugs (NSAIDs), or medicines that contain azathioprine or 6-mercaptopurine. Taking mesalamine suppositories with NSAIDs may cause kidney problems. Taking mesalamine suppositories with azathioprine or 6-mercaptopurine may cause blood problems. Your doctor may do certain tests during treatment with mesalamine suppositories.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I use mesalamine suppositories?

- Use mesalamine suppositories exactly as prescribed by your doctor. Your doctor will tell you how long to continue using mesalamine suppositories.
- Mesalamine comes as a suppository that you insert into your rectum.
- **Do not** cut or break the suppository.
- Use mesalamine suppositories 1 time each day at bedtime, for 3 to 6 weeks. It is not known if mesalamine suppositories are safe and effective for use for longer than 6 weeks.
- After you insert mesalamine suppository in your rectum, try to keep (retain) the suppository in your rectum for 1 to 3 hours or longer if possible.
- If you miss a dose of mesalamine suppositories, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose. Take the next dose at your regular time. Do not take 2 doses at the same time.
- Mesalamine suppositories can stain surfaces including clothing and other fabrics, flooring, painted surfaces, marble, granite, vinyl and enamel. Keep mesalamine suppositories away from these surfaces to prevent staining.

What are the possible side effects of mesalamine suppositories?

Mesalamine suppositories may cause serious side effects, including:

- **Kidney problems.** Your doctor will do certain tests before you start using mesalamine suppositories and during your treatment with mesalamine suppositories.
- **Acute Intolerance Syndrome or Other Allergic Reactions.** Some people who use mesalamine suppositories can have allergic type reactions, including "Acute Intolerance Syndrome." Other allergic reactions can cause heart problems including an inflammation of the sac around the heart (pericarditis), blood problems, and problems with other organs in the body including the kidneys, liver and lungs. These problems usually happen in people who have had an allergic reaction to medicines containing sulfasalazine. Stop using mesalamine suppositories and tell your doctor right away if you get any of these symptoms:
 - o cramps
 - o fever
 - o stomach (abdominal) pain
 - o headache
 - o bloody diarrhea
 - o rash
 - o chest pain
 - o shortness of breath
 - o decrease in the amount of urine
 - o fatigue

- **Liver problems.** This can happen in people who have a history of liver problems and have taken other medicines that contain mesalamine. Tell your doctor right away if you get any of these symptoms while using mesalamine suppositories:

- o yellowing of your eyes
- o flu-like symptoms
- o itchy skin
- o nausea or vomiting
- o feeling very tired

The most common side effects of mesalamine suppositories include:

- o dizziness
- o rectal pain
- o acne
- o fever
- o inflammation of the large intestine (colitis)
- o rash

These are not all of the possible side effects of mesalamine suppositories.

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

How should I store mesalamine suppositories?

- Store mesalamine suppositories at room temperature below 77°F (25°C).
- Mesalamine suppositories may be refrigerated.
- Keep mesalamine suppositories away from direct heat, light, or humidity.

Keep mesalamine suppositories and all medicines out of the reach of children.

General information about the safe and effective use of mesalamine suppositories.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use mesalamine suppositories for a condition for which it was not prescribed. Do not give mesalamine suppositories to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your doctor or pharmacist for information about mesalamine suppositories that is written for health professionals.

For more information, call Annora Pharma Private Limited at 1-866-495-1995.

What are the ingredients in mesalamine suppositories?

Active ingredients: mesalamine

Inactive ingredients: Hard Fat base

Patient Information available at <http://camberpharma.com/medication-guides>



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This Patient Information has been approved by the U.S. Food and Drug Administration.

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