What is CANASA®?

CANASA (mesalamine) 1000 mg rectal suppository is a prescription medicine used to treat adults with mildly to moderately active ulcerative proctitis (ulcerative rectal colitis). It is not known if CANASA is safe and effective in children.

IMPORTANT RISK INFORMATION

Do not use CANASA if you are:

- allergic to medicines that contain salicylates, including aspirin.
- allergic to mesalamine or any of the ingredients in CANASA.

Please also see Important Risk Information throughout and Patient Information within the enclosed full Prescribing Information.
Understanding ulcerative proctitis

Ulcerative proctitis (UP), is inflammation or swelling of the rectum (the area between the colon and the anus). This inflammation may cause symptoms like bleeding, stomach pain, diarrhea, and urgency (a sudden urge to go to the bathroom). Up to 250,000 people in the United States may suffer from UP each year.

What causes ulcerative proctitis?

The exact cause of ulcerative proctitis is unknown, but researchers believe:

• Foreign substances (eg, bacteria or a virus) may react with the body’s immune system, triggering inflammation of the rectum, which causes the symptoms of ulcerative proctitis
• Ulcerative proctitis may run in families

Ulcerative proctitis is not caused by emotional stress or eating certain foods. However, stress and certain foods may trigger or worsen symptoms in some people.

Talking to your doctor

It is important to talk to your doctor about the symptoms you may be experiencing so that he or she can select an appropriate treatment option.

Common symptoms of UP include:
• Streaks of blood or mucus in stool
• Stomach (abdominal) pain
• Diarrhea
• Urgency
• Urgency without being able to go

UP cannot be cured, but there are ways to help your symptoms.

Treatment for UP

There will be times in your life when UP is active and times when you have no symptoms. The good news is that there are treatments available that may bring relief. To help you relieve your UP symptoms, your doctor may give you medicine. Your doctor may also suggest lifestyle changes, such as changing your diet and exercising.
CANASA (mesalamine): For relief of UP
CANASA is a prescription medicine used to treat mildly to moderately active UP in adults.

IMPORTANT RISK INFORMATION (continued)
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Ask your doctor if you are not sure if your medicine is listed.

How CANASA may work
CANASA is a suppository that is inserted directly into the rectum once a day at bedtime. The way CANASA works is not known, but it is thought to deliver medicine directly to the rectal area to help treat symptoms of mildly to moderately active UP.

Please also see Important Risk Information throughout and Patient Information within the enclosed full Prescribing Information.
IMPORTANT RISK INFORMATION (continued)

Before using CANASA, 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 CANASA can harm your unborn baby.
- are breastfeeding or plan to breastfeed. CANASA can pass into your breast milk. Talk to your doctor about the best way to feed your baby if you use CANASA.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking CANASA with nonsteroidal anti-inflammatory drugs (NSAIDs) may cause kidney problems. Taking CANASA with azathioprine or 6-mercaptopurine may cause blood problems. Your doctor may do certain tests during treatment with CANASA.

How to use CANASA

Follow your doctor’s instructions about how often and how long to use CANASA. Follow these steps to use CANASA:

1. Have a bowel movement just before using CANASA at bedtime
2. Detach 1 CANASA suppository from the strip of suppositories
3. Hold the suppository upright and carefully peel open the plastic at the precut line to remove the suppository
4. Using gentle pressure, insert the pointed end of the suppository completely into your rectum
5. Keep (retain) the suppository in your rectum for 1 to 3 hours or longer, if possible

Do not handle the suppository too much because it may begin to melt from the heat of your hands and body. CANASA can cause staining of clothing, other fabrics, and other surfaces.

If you miss a dose of CANASA, use it as soon as possible, unless it is almost time for the next dose. Do not use 2 CANASA suppositories at the same time to make up for a missed dose.
Staying on the right track gives you a better chance for success

CANASA should be used once daily at bedtime as directed by your doctor. It’s important to know that even if your UP symptoms are getting better, the disease may still be active. That’s why it’s important to continue using CANASA for 3 to 6 weeks, as directed by your doctor.

Studies show that using CANASA for up to 6 weeks may help improve rectal inflammation and deliver relief of symptoms such as rectal bleeding and number of bowel movements.

Remember:

Even if you start feeling better, you should still use CANASA exactly as your doctor has directed, for as long as you have been instructed to use it.

IMPORTANT RISK INFORMATION (continued)

What are the possible side effects of CANASA?

CANASA may cause serious side effects, including:

• **Kidney Problems.** Your doctor will do certain tests before you start using CANASA and during your treatment.

• **Acute Intolerance Syndrome or Other Allergic Reactions.** When this happens, it is usually in people who have had an allergic reaction to sulfasalazine. Stop using CANASA and tell your doctor right away if you get any of these symptoms: cramps, stomach (abdominal) pain, bloody diarrhea, chest pain, decrease in the amount of urine, fever, headache, rash, shortness of breath, or 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 CANASA: yellowing of your eyes, itchy skin, feeling very tired, flu-like symptoms, nausea or vomiting.
What else can I do?

Change your diet

Taking medicine is an important part of managing UP. There are also other things you can do to stay healthy. For instance, people with UP can lose nutrients and fluids, so be sure to drink enough fluids and eat a well-balanced diet. Stay away from foods and drinks that may make your symptoms worse, such as:

- Spicy foods
- Alcohol
- Gassy foods, like beans and broccoli
- Caffeinated drinks
- Milk products
- Carbonated drinks, like soda

Reduce stress

While stress does not cause UP, it can set off symptoms or make them worse. Stressful events can’t always be avoided; however, you can choose healthier ways of coping with stress.

- Exercise can reduce stress and depression, and help the digestive system work more normally
- Hypnosis, meditation, and other relaxation techniques can also relieve stress
- Support groups and/or counseling can be helpful, especially in learning how others deal with UP

You may be eligible to save on your CANASA prescriptions.

Visit www.canasa.com for more information.
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When ulcerative proctitis (UP) symptoms flare, CANASA delivers relief
• CANASA may provide relief of mildly to moderately active UP
• Topical treatments, like CANASA, are thought to work at the site of inflammation
• You may be eligible to save on your CANASA prescriptions

The most common side effects of CANASA include: dizziness, acne, inflammation of the large intestine (colitis), rectal pain, fever, and rash.

Visit www.canasa.com for more information.

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