

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

ASACOL ENEMA, 2 g/50 ml, rectal suspension.

mesalazine (5-aminosalicylic acid).

Antioxidant: Sodium metabisulphite 0,05 g

Read all of this leaflet carefully before you start using ASACOL ENEMA

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ASACOL ENEMA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ASACOL ENEMA is and what it is used for
2. What you need to know before you use ASACOL ENEMA
3. How to use ASACOL ENEMA
4. Possible side effects
5. How to store ASACOL ENEMA
6. Contents of the pack and other information

1. What ASACOL ENEMA is and what it is used for

ASACOL ENEMA contains mesalazine, which is an anti-inflammatory medicine used for: The treatment and maintenance of remission in ulcerative colitis.

Ulcerative colitis is a disease of the large bowel (colon) and back passage (rectum), in which the lining of the bowel becomes inflamed (red and swollen). ASACOL ENEMA act locally in the rectum to reduce this inflammation.

ASACOL ENEMA can also be used to prevent further episodes of ulcerative colitis.

2. What you need to know before you use ASACOL ENEMA

Do not use ASACOL ENEMA:

- If you are hypersensitive (allergic) to mesalazine or to the other ingredients of ASACOL ENEMA (see section 6).
- If you are hypersensitive (allergic) to aspirin or other salicylates.
- If you have had serious kidney or liver problems.
- If you are pregnant or breastfeeding your infant.
- This medicine should not be used by children.

Warnings and precautions

Take special care with ASACOL ENEMA:

When you start using ASACOL ENEMA and during treatment with ASACOL ENEMA, your doctor may consider regular examinations to check that your blood, liver, kidneys and lungs are functioning normal. It is recommended that you keep all appointments for tests arranged by your doctor. The treatment will be stopped if it affects your liver or kidneys.

Tell your doctor before you start using ASACOL ENEMA if you are affected by any of the following conditions or diseases, especially:

- If you have ever had any kidney problems, especially if you are elderly.
Kidney stones may develop with use of ASACOL ENEMA. Symptoms may include pain in sides of abdomen and blood in urine. Take care to drink sufficient amounts of liquid during treatment with ASACOL ENEMA.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using ASACOL ENEMA.
- If you have liver problems.
- Serious blood problems have been reported with the use of ASACOL ENEMA. Your doctor may perform regular blood tests when you are using ASACOL ENEMA to check if your blood counts (the number of cells in the blood) are normal. Treatment with ASACOL ENEMA must be stopped immediately if you experience signs of unexplained bleeding, bruising, purple-coloured spots and patches that occur on your skin and persistent sore throat.

- If you have any lung disease, such as asthma.
- If you have had an allergic reaction in the past that has manifested itself as inflammation of the heart muscle or heart lining (pericardium). If you have had an allergic heart reaction caused by ASACOL in the past, you must not use ASACOL ENEMA. If you have had an allergic heart reaction in the past that was not caused by ASACOL, you may use ASACOL ENEMA, but extra care should be taken.
- If you have a history of hypersensitivity (allergy) to sulphasalazine. Treatment with ASACOL ENEMA must be stopped immediately if you experience acute symptoms of intolerance such as stomach cramps, acute stomach pain, fever, severe headache or rash.
- If you have ulcers in the stomach or duodenum, extra care should be taken when using ASACOL ENEMA.
- ASACOL ENEMA may interact with other medicines such as azathioprine (an immunosuppressant), as well as mercaptopurine (medicines to treat cancer) see “Other medicines and ASACOL ENEMA”.
- If you are on medication that may affect kidney function e.g., Nonsteroidal anti-inflammatory drugs (NSAIDs) such as aspirin.

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis have been reported in association with ASACOL ENEMA treatment. Stop using ASACOL ENEMA and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Children

ASACOL ENEMA should not be used in children as safety and efficacy has not been established.

Other medicines and ASACOL ENEMA

Always tell your healthcare professional if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

- Medicines affecting the immune system (e.g. azathioprine or 6-mercaptopurine or thioguanine);
- Medicines that prevent the formation of blood clots (anticoagulants, e.g warfarin);
- Medicines for pain and inflammation (NSAIDs).

ASACOL ENEMA with food, drink and alcohol

The consumption of food, drink and alcohol does not interfere with the use of ASACOL ENEMA.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using ASACOL ENEMA.

Safety in pregnancy and breastfeeding has not been established.

Driving and using machinery

ASACOL ENEMA have no or negligible influence on the ability to drive and use machines.

ASACOL ENEMA contains sodium benzoate

ASACOL ENEMA contains 100 mg of sodium benzoate per dose, equivalent to 100 mg/100 ml. Sodium benzoate may cause local irritation.

3. How to use ASACOL ENEMA

Do not share medicines prescribed for you with any other person.

Always use ASACOL ENEMA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of ASACOL ENEMA is too strong or too weak, talk to your doctor or pharmacist.

The enemas are for rectal use and must not be swallowed.

Mode of administration

Before using the enema: The bottle should be warmed to body temperature in a basin or bowl of warm water for about 10 minutes. The bottle should be shaken well immediately before inserting the enema.

Inserting the enema: The screw cap must be twisted off from the bottle and the applicator tip must be twisted on. The applicator tip can be lubricated with vaseline. For the enema administration the patient should lie on the left side with

the left leg extended and the right leg bent. After inserting the applicator tip into the rectum the liquid should be pressed out gently and slowly. The tip should be withdrawn with the container still compressed. The patients should try to stay in the administration position for 5 to 10 minutes or until the urge to pass the enema has disappeared. The enema should be retained in the bowel if possible without evacuation of the bowels until the next morning.

The usual adult dosage of ASACOL ENEMA is: Two gram (one 50 ml container) administered at night per rectum.

The pharmacist's label on your carton will tell you how many enemas your doctor would like you to use. Please read the label carefully. **Do not use more enemas than your doctor has recommended.**

ASACOL ENEMA is not recommended for children.

Keep using your enema until the prescribed course is finished. Your symptoms may come back if you stop your treatment too early.

If you use more ASACOL ENEMA than you should

You should only use as many enemas as your doctor or pharmacist has told you. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take your enema bottle with you.

If you forget to use ASACOL ENEMA

If you forget to administer the enema at the right time, insert it as soon as you remember. Then go on as before. Do not use a double dose to make up for forgotten individual doses. If you have any doubts speak to your doctor or pharmacist for advice.

If you stop using ASACOL ENEMA

Do not stop using ASACOL ENEMA without talking to your doctor first even if you feel better. If you have any further questions on the use of ASACOL ENEMA, ask your doctor or pharmacist.

4. Possible side effects

ASACOL ENEMA can have side effects.

Not all side effects reported for ASACOL ENEMA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using ASACOL ENEMA, please consult your healthcare provider for advice.

Organ specific side effects affecting the heart, lungs liver, kidneys, pancreas, skin and subcutaneous tissue have been reported.

If any of the following happens, stop using ASACOL ENEMA and tell your doctor **immediately** or go to the casualty department at your nearest hospital:

- Unusual bleeding (e.g., unexplained nose bleeds) or you start to develop unexplained bruising (without injury)
- Fever (high temperature) or sore throat
- Bleeding under your skin, purple spots or patches under your skin
- Anaemia (feeling tired, weak and looking pale, especially on your lips, nails and inside of eyelids)
- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms.
- Flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)).

Allergic reactions to mesalazine as contained in ASACOL ENEMA can occur. Tell your doctor if you get a rash (with or without itching), any shortness of breath, palpitations (rapid heartbeat) or chest pain. These effects will usually disappear when ASACOL ENEMA is stopped.

Tell your doctor if you notice any of the following:

Less frequent side effects

- Severely reduced blood cell count can cause weakness, bruising or increase the risk of infection; low counts of blood cells; decrease of platelets counts increases the risk of bleeding
- Allergic reactions such as rash or skin eruption
- Fever that occurs while taking this medicine and which disappears when the medicine is stopped (drug fever)

- Immune system disease that can involve organs and joints
- Headache
- Dizziness
- Inflammation of the heart with signs like chest pains and palpitations
- Inflammation of the heart sac
- Diarrhoea, stomach pain, wind (flatulence), feeling sick (nausea), vomiting
- Increased sensitivity of your skin to sun and ultraviolet light (photosensitivity)
- Swelling around the eyes and in the feet and ankles, foamy urine and weight gain due to excess fluid retention (nephrotic syndrome) which may be reversible on withdrawal
- Ulcerative colitis involving the entire large intestine
- Damaged nerves giving a sensation of numbness and tingling
- Lung disease (scarring of lung tissue, allergic reaction) resulting in difficulty in breathing, cough, wheezing and collection of fluid in the lungs, pneumonia
- Inflamed pancreas associated with pain in upper abdomen and back and feeling sick (nausea)
- Abnormal liver function tests, hepatitis (inflammation of the liver giving rise to flu-like symptoms and jaundice)
- Hair loss
- Muscle or joint pain
- Kidney problems (such as inflammation and scarring of the kidney), reduced kidney function, which may be reversible if treatment is stopped early
- Reversible decrease in sperm production

Frequency not known

- Chest pain that worsens during breathing (pleurisy)
- Intolerance to mesalazine contained in ASACOL ENEMA sometimes with worsening symptoms of underlying disease
- Local reaction

- Kidney stones and associated kidney pain (see also section 2)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of ASACOL ENEMA.

5. How to store ASACOL ENEMA

Store at or below 25 °C and protect from light.

Store all medicines out of reach of children.

Do not use the enema after the expiry date printed on the container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g., toilets).

6. Contents of pack and other information

What ASACOL ENEMA contains

The active substance is mesalazine (also known as 5-aminosalicylic acid).

The other ingredients are sodium benzoate, sodium metabisulfite, purified water, xanthan gum.

What ASACOL ENEMA looks like and contents of the pack

A pale brown-pink, slightly aerated, suspension with a slightly acrid odour.

50 ml single enema.

Holder of Certificate of Registration

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