PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

PENTASA 1 g, Suppositories

Mesalazine

Read all of this leaflet carefully before you start using PENTASA® 1 g Suppositories.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse of other health care provider.
- PENTASA® 1 g Suppositories 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 PENTASA® 1 g Suppositories are and what it is used for

PENTASA® 1 g Suppositories contains the active mesalazine that belongs to a group of medicines called salicylates (anti-inflammatory agents).

PENTASA® 1 g Suppositories are indicated in the treatment of mild to moderate ulcerative proctitis (inflammation of the back passage (rectum)) where the lesions are within 30 cm of the anal verge and to prevent from further attacks.

The suppositories release the active ingredient slowly which then acts locally to reduce the inflammation

and help relieve or stop the pain.

2. What you need to know before you use PENTASA® 1 g Suppositories

Do not use PENTASA® 1 g Suppositories:

- if you are hypersensitive (allergic) to mesalazine, salicylates or any of the ingredients of PENTASA® 1 g Suppositories (listed in section 6).
- if you suffer from severe liver or kidney impairment.

Warning and precautions

Take special care with PENTASA® 1 g Suppositories:

- if you develop any kidney problems during the start of this treatment
- if you currently have, or previously had liver or kidney disease
- if you experience strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears contact your doctor immediately.
- if you develop unexplained bleeding (e.g. nose bleeds), bruises, purple discolouration of the skin, sore throat, fever, chest pains, rapid or irregular heartbeat and shortness of breath
- if you are on any medication that may affect kidney function e.g. non-steroidal anti-inflammatory medicine (NSAIDs) such as aspirin, and azathioprine
- if you have ever had an allergy to a medication called sulphasalazine
- if you suddenly develop abdominal cramps, abdominal pain, fever, severe headache and rash, **stop using** PENTASA® 1 g Suppositories and seek medical advice immediately.
- if you have lung problems, in particular asthma.

Serious skin reactions including Drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN) have been reported in association with PENTASA® 1 g Suppositories treatment. Stop using PENTASA® 1 g Suppositories and seek medical

attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Patients suffering from inflammation of the digestive tract are at risk of developing kidney stones (a small, hard deposit that forms in the kidneys and is often painful when passed).
While you are on treatment with PENTASA® 1 g Suppositories, you should avoid becoming dehydrated (this is when your body loses too much water). This can occur due to severe or prolonged attacks of vomiting and or diarrhoea, high fever or heavy sweating. Should this occur, ask your doctor, nurse or pharmacist for advice as soon as possible.

Mesalazine (as contained in PENTASA® 1 g Suppositories) may produce red-brown urine discoloration after contact with sodium hypochlorite bleach in the toilet water. It concerns a chemical reaction between mesalazine and bleach and is harmless.

Caution is advised during the use of PENTASA® 1 g Suppositories in the elderly.

If you are using these suppositories on a long term basis, your doctor may want to carry out a number of tests from time to time. This is quite usual and nothing to worry about.

Children and adolescents

The use in children and adolescents are not recommended.

Other medicines and PENTASA® 1 g Suppositories

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

This is especially important if you are taking any of the following:

- Medicine that may affect kidney function e.g. azathioprine, mercaptopurine and thioguanine

- NSAID's (non-steroidal anti-inflammatory drugs) e.g. aspirin.
- Preparations which lower stool pH, e.g. lactulose
- Certain medicines that inhibit blood clotting (medicines for thrombosis or to thin your blood, e.g. warfarin)

Pregnancy and breastfeeding

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 health care provider for advice before using PENTASA® 1 g Suppositories.

PENTASA® 1 g Suppositories should be used with caution if you are pregnant or suspect that you are pregnant. Contact you doctor should you become pregnant while using PENTASA® 1 g Suppositories.
PENTASA® 1 g Suppositories should be used with caution if you are breastfeeding.

Driving and using machines

It is not always possible to predict to what extent PENTASA® 1 g Suppositories. may interfere with the daily activities of a patient. No effects on the ability to drive and use machines have been observed with PENTASA® 1 g Suppositories.

3. How to use PENTASA® 1 g Suppositories

Do not share medicines prescribed for you with any other person.
Always use PENTASA® 1 g Suppositories exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Your doctor will tell you how long your treatment with PENTASA® 1 g Suppositories will last. Do not stop treatment early as your symptoms will return. If you have the impression that the effect of PENTASA® 1 g Suppositories is too strong or too weak, tell your doctor or pharmacist.

PENTASA ® 1 g Suppositories should be inserted into the rectum (back passage). They should not be taken by mouth.

There is no special time of day to insert PENTASA® 1 g Suppositories. They are intended to remain in place for as long as possible. It is therefore usually best to insert a suppository before going to sleep.

Adults

Usually your doctor will prescribe one PENTASA® 1 g Suppository daily for two to four weeks for the treatment of an attack of colitis, or for longer to help prevent another attack.

You should go to the toilet to empty your bowels and bladder (if necessary) before inserting the suppository.

1. Open the foil pack.
2. Put a protector on the finger with which you will insert the suppository.
3. Insertion may be easier if you moisten the suppository with water first.
4. Insert the suppository gently and fully into the back passage. It may help to lie down on one side and raise the other knee. Rest the raised knee on the floor or pillow.
5. Remain still for a few minutes after insertion to help keep in the suppository. If it comes out within 10 minutes, a new one should be inserted.
6. Dispose of the opened foil pack and the used finger protector safely and wash your hands.

If you use more PENTASA® 1 g Suppositories than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison centre.

If you forget to use PENTASA® 1 g Suppositories

If you forget to insert a dose, insert it as soon as you remember. Do not insert a double or larger dose to make up for the forgotten individual doses. Continue to insert the next suppository at the usual time.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

4. Possible side effects

PENTASA® 1 g Suppositories can have side effects.

Not all side effects reported for PENTASA® 1 g Suppositories are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using PENTASA® 1 g Suppositories, please consult your health care provider for advice.

If any of the following happens, stop using PENTASA® 1 g Suppositories and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Sudden signs of allergic reactions such as rash, itching or hives, shortness of breath, coughing, chest tightness or wheezing, dizziness, fainting, rapid or weak heartbeat, swelling of the limbs, face, lips, mouth and throat which may cause difficulty swallowing or breathing.
- severe stomach cramps and/or pain, bloody diarrhoea, fever, severe headache and skin rash.
- 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, widespread rash, fever and enlarged lymph nodes. These serious skin rashes can be preceded by fever and flu-like symptoms.

These are all very serious side effects. If you have them, you may have had a serious reaction to PENTASA® 1 g Suppositories. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Bruising easily, unusual bleeding (e.g., nosebleeds), or frequent signs of infection such as fever, chills, sore throat and mouth ulcers (signs of blood disorders).
- chest pain sometimes spreading to the neck and shoulders, with fever, shortness of breath, excess tiredness and rapid or irregular heartbeat (signs of heart problems)

- difficulty breathing
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Following rectal administration local reactions such as itching, rectal discomfort and urge may occur.

Frequent side effects:

- headache, dizziness
- diarrhoea, abdominal pain, nausea, vomiting, flatulence
- rash
- rectum discomfort and irritation at the application site; an uncomfortable, irritating, itchy sensation in your rectum; a feeling of being unable to empty the large bowel, even if there is no remaining stool to expel.

Less frequent side effects

- numbness and tingling in hands and feet, muscle weakness and loss of balance
- abdominal pain that radiates to your back and worsens after eating, fever
- red or purple spots around the corners of the lips; swelling or cracking at the corners of the lips
- black tarry stools (because of intestinal bleeding)
- pink or red skin rash with blotchy blisters, scaly patches, or raised spots on areas the light touched
- hair loss
- a condition (erythema multiforme) characterised by high temperature, headache, feeling generally unwell, raw sores inside your mouth, making it hard to eat and drink, swollen lips covered in crust
- a condition (Stevens-Johnson Syndrome) characterised by skin pain, rash, blisters
- a condition (Toxic epidermal necrolysis (TEN)) characterised by painful, life-threatening skin condition – large areas of blistering and peeling skin

- blood disorders e.g. anaemia (fatigue, weakness), leukopenia (sore throat, skin sores, fever and chills)
- lung reactions like coughing, tightness in the chest, wheezing
- muscle pain
- kidney disorders including nephritis (kidney inflammation), kidney function impairment, urine discolouration.
- male infertility characterised by low sperm count.
- a condition called pancolitis characterised by exhaustion, abnormal weight loss, pain and cramps in your stomach and abdomen, strong and frequent bowel movement.
- Systemic lupus erythematosus (SLE) - most common type of lupus. It is an autoimmune disease in which the immune system attacks its own tissues, causing widespread inflammation and tissue damage in the affected organs. It can affect the joints, skin, brain, lungs, kidneys, and blood vessels
- a severe side effect characterised by an extensive skin rash in association with soft internal organs of the body involvement, lymph node swelling, changes to your blood composition (DRESS)
- kidney stones and associated kidney pain

Side effects with unknown frequency:

- if you experience strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears. These could be symptoms of increased pressure within your skull (idiopathic intracranial hypertension).

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 health care provider. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of PENTASA® 1 g Suppositories.

5. How to store PENTASA® 1 g Suppositories

Store all medicines out of reach of children.

- Store at or below 25 °C and protect from light. Do not refrigerate.
- Do not remove the suppositories from the package until required for use.
- Do not use the suppositories after the expiry date printed on the blisters. Decomposed products may be toxic.
- Do not store in a bathroom
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PENTASA® 1 g Suppositories contains:

The active substance is mesalazine.

Each suppository contains 1 g mesalazine.

The other ingredients are povidone, purified water, macrogol 6000, magnesium stearate and talc.

What PENTASA® 1 g Suppositories looks like and contents of the pack

White to tan, spotted, oblong suppositories.

28 Suppositories per carton.

PENTASA® 1 g Suppositories are packed in double aluminium foil blisters, each strip containing 7 suppositories. Four blisters are placed into an outer carton.

Holder of the Certificate of Registration

Ferring (Pty) Ltd.

Route 21 Corporate Park

6 Regency Drive

Irene Ext 30

Pretoria

Gauteng, 0157

Tel. nr.: +27 12 345 6358

This leaflet was revised in

24 March 2026

Registration number

A40/11/0374

Namibia NS2 Reg No/Nr.: 10/11/0483