

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

PENTASA® SACHETS 2 g, Prolonged release granules

PENTASA® SACHETS 4 g, Prolonged release granules

Mesalazine

Sugar free

Read all of this leaflet carefully before you start taking PENTASA® SACHETS 2 g & 4 g

- 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.
- PENTASA® SACHETS 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® SACHETS are and what it is used for
2. What you need to know before you take PENTASA® SACHETS
3. How to take PENTASA® SACHETS
4. Possible side effects
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6. Contents of the pack and other information

1. What PENTASA® SACHETS are and what it is used for

PENTASA® SACHETS are used in adults and children over 6 years of age to treat Crohn's disease and ulcerative colitis, diseases associated with inflammation, ulcers and sores in the bowel causing bleeding, stomach pain, and diarrhoea.

The active ingredient in this medicine is mesalazine. It is an anti-inflammatory medicine, chemically similar to aspirin, and is thought to work by reducing inflammation in the bowel.

2. What you need to know before you take PENTASA® SACHETS

Do not take PENTASA® SACHETS:

- if you are hypersensitive (allergic) to mesalazine, aspirin-like medicines or any of the other ingredients of PENTASA® SACHETS (listed in section 6).
- if you have a severe kidney or liver problem.

Warnings and precautions

Take special care with PENTASA® SACHETS:

- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking mesalazine as contained in PENTASA® SACHETS, tell your doctor before taking PENTASA® SACHETS. 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® SACHETS. Stop taking PENTASA® SACHETS and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions (see section 4).
- If you suddenly develop abdominal cramps, abdominal pain, fever, severe headache, and skin rashes, which may be signs of a hypersensitivity reaction, stop taking PENTASA® SACHETS and seek medical advice immediately.
- If you experience chest pains, rapid or irregular heartbeat, excess tiredness, and shortness of breath, which may be signs of a hypersensitivity reaction affecting your heart, stop taking PENTASA® SACHETS and contact your doctor immediately.
- If you develop unexplained bleeding (e.g., nose bleeds), bruises, purple discolouration of the skin, sore throat, and fever, which may be signs of serious blood disorders, stop taking PENTASA® SACHETS

and contact your doctor immediately.

- If you have mild kidney or mild liver problems.
- If you have a history of lung disease, in particular asthma.
- If you have an active peptic ulcer (stomach ulcer or duodenal ulcer)
- If you are on medication that may affect kidney function e.g., non-steroidal anti-inflammatory medicine (NSAIDs) such as aspirin and azathioprine.
- If you are allergic to sulphasalazine (due to the risk of allergy to salicylates).
- If you experience strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears contact your doctor immediately.
- Kidney stones may develop with use of PENTASA® SACHETS. Symptoms may include pain in sides of abdomen and blood in urine. Take care to drink sufficient amounts of liquid during treatment with PENTASA® SACHETS.

Mesalazine (as contained in PENTASA® SACHETS) 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.

Your doctor will draw blood and test your liver and kidney function before and during treatment with PENTASA® SACHETS.

If you are about to start any new treatment or medication, remind your doctor, dentist and pharmacist that you are taking PENTASA® SACHETS.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using PENTASA® SACHETS. Caution is advised during the use of PENTASA® SACHETS in the elderly.

Children and adolescents

PENTASA® SACHETS is not recommended for children younger than 6 years because safety has not been

established.

Other medicines and PENTASA® SACHETS

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

Mesalazine belongs to a group of medicines called salicylates that may interfere with the following types of medicines:

- azathioprine, used to suppress the immune system
- NSAID's (non-steroidal anti-inflammatory drugs) e.g. aspirin
- 6-mercaptopurine, used to treat leukaemia
- thioguanine, used to treat leukaemia
- warfarin, a blood thinner used to reduce the formation of blood clots.

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 taking this medicine.

There is limited experience with the use of PENTASA® SACHETS during pregnancy and breastfeeding and should therefore be used with caution.

Blood disorders have been reported in new-borns of mothers being treated with PENTASA® SACHETS. The new-born may develop allergic reactions after breastfeeding, e.g., diarrhoea. If the new-born develops diarrhoea, breastfeeding should be discontinued.

Animal studies show that mesalazine does not affect the ability to have babies in males or females.

Driving and using machines

PENTASA® SACHETS is not expected to affect your ability to drive a car or operate machinery.

It is not always possible to predict to what extent PENTASA® SACHETS may interfere with your daily

activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which PENTASA® SACHETS affects you.

3. How to take PENTASA® SACHETS

Do not share PENTASA® SACHETS with any other person.

PENTASA® SACHETS granules must not be chewed or crushed. The contents of PENTASA® SACHETS should be emptied on the tongue and washed down with some water or juice. Alternatively mix the entire content of the sachet with yogurt and take immediately without chewing on the granules.

The dose and directions of PENTASA® SACHETS will be different for different patients and may depend on what the medicine is being used for and if other medicines are also being taken.

Always take PENTASA® SACHETS exactly as your doctor or pharmacist has told you.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to use:

Use as directed by your doctor.

Do not stop using PENTASA® SACHETS or lower the dosage without checking with your doctor first. If you stop using it suddenly, your condition may worsen.

Ulcerative colitis

Adults:

To treat an attack of colitis, your doctor will prescribe a dose of up to 4 g PENTASA® SACHETS once a day or in divided doses. This may be taken as two PENTASA® SACHETS 2 g or one PENTASA® SACHETS 4 g.

To help maintain freedom from further attacks, your doctor will usually prescribe 2 g mesalazine a day administered as one PENTASA® SACHETS 2 g once daily or in divided doses.

Children 6 years of age and older:

For an attack of ulcerative colitis and to help maintain freedom from further attacks, the dose for children will be calculated by your doctor and depends on the child's weight. It is generally recommended that half the adult dose is given to children with a body weight of up to 40 kg and the normal adult dose to children with a body weight above 40 kg. The total dose should not exceed 4 g/day (maximum adult dose) for an attack of colitis and 2 g/day (recommended adult dose) to maintain freedom from further attacks.

Crohn's Disease

Adults:

To treat an attack of Crohn's disease and to help maintain freedom from further attacks, your doctor will usually prescribe 4 g mesalazine a day administered as two PENTASA® SACHETS 2 g in divided doses.

Children 6 years of age and older:

For an attack of Crohn's disease and to help maintain freedom from further attacks, the dose for children will be calculated by your doctor and depends on the child's weight. It is generally recommended that half the adult dose is given to children with a body weight of up to 40 kg and the normal adult dose to children with a body weight above 40 kg. The total dose should not exceed 4 g/day (recommended adult dose).

If you take more PENTASA® SACHETS than you should

In the event of overdosage, contact your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre immediately. Take this leaflet and any sachets with you, so that the doctor knows what you have taken.

If you forget to take your PENTASA® SACHETS

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would

normally.

If you are not sure what to do, ask your doctor or pharmacist.

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

If you stop taking PENTASA® SACHETS

Continue using your medicine for as long as your doctor tells you.

This medicine helps to control your condition but does not cure it. It is important to keep using your medicine even if you feel well.

4. Possible side effects

PENTASA® SACHETS can have side effects. Allergic reactions may occur and are very serious.

Not all side effects reported for PENTASA® SACHETS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PENTASA® SACHETS, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking PENTASA® SACHETS 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,
- 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 and shortness of breath, excess tiredness and rapid or irregular heartbeat (signs of heart problems),
- a change in the colour or amount of urine produced (signs of kidney problems).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache
- diarrhoea
- abdominal pain
- nausea or vomiting
- rash
- flatulence (passing wind).

Less frequent side effects:

- increased sensitivity of your skin to sun and ultraviolet light (photosensitivity)
- semen with a low concentration of sperm (oligospermia) (this is reversible).
- inflammation of the pancreas, symptoms may include back and/or stomach pain
- increased amylase in your blood and/or urine (enzyme that helps digest carbohydrates)
- dizziness
- anaemia which is characterised by a decrease in the number of red blood cells (symptoms may include extreme tiredness, and weakness)
- liver disorders including an increase in liver enzymes, no or reduced flow of bile, inflammation, scarring and failure of the liver (symptoms may include jaundice characterised by yellowing of the skin and/or eyes, dark coloured urine, and/or pale bowel motions)

- kidney disorders including inflammation of the kidneys (symptoms may include blood in the urine, and/or swelling due to build-up of fluid)
- lupus erythematosus (an auto-immune disorder effecting the skin)
- numbness, tingling or weakness of the arms and legs (peripheral neuropathy)
- 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).
- allergic and fibrotic lung reactions, inflammation of the lining of the lungs or lung scarring (symptoms may include coughing, bronchospasm, chest discomfort or pain on breathing, breathing difficulties, bloody and/or excessive phlegm)
- pancolitis which is a kind of inflammatory bowel disorder (IBD) that affects the entire internal lining of the large bowel called (symptoms may include exhaustion, abnormal weight loss, fever, pain and cramps in your stomach and abdomen, strong and frequent bowel movement that may contain blood)
- fever
- muscle aches and pains
- painful joints
- hair loss (reversible).

Frequency not known:

- 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 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® SACHETS.

5. How to store PENTASA® SACHETS

- Store all medicines out of reach of children.
- Store at or below 25 °C in the original package. Protect from light.
- Please return expired medicine or partially used medicine to your pharmacist for safe disposal.

6. Contents of the pack and other information

What PENTASA® SACHETS contain:

- The active substance is mesalazine. Each sachet contains 2 g or 4 g mesalazine.
- The other ingredients are ethylcellulose, and povidone.

What PENTASA® SACHETS look like and contents of the pack

White-grey to pale white-brown cylindrical shaped granules.

The granules are filled into tight, polyester/aluminium/LD polyethylene sachets.

2 g sachet: 10 or 60 sachets are placed into a cardboard carton.

4 g sachet: 10, 20, 30, 50 or 100 sachets are placed into a cardboard carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Ferring (Pty) Ltd

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Ferring (Pty) Ltd.
Pentasa Sachets 2 g – 43/11/0014
Pentasa Sachets 4 g – 56/11/1135
Each sachet contains 2 g or 4 g mesalazine

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