

FINAL PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

PENTASA® 500 mg tablets

Read all of this leaflet carefully before you start taking PENTASA® 500 mg tablets

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- **PENTASA® 500 mg** tablets have 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 PENTASA® 500 mg TABLETS CONTAIN

The active substance is:

Each tablet contains 500 mg mesalazine.

The other ingredients are:

Magnesium stearate, talc, ethylcellulose, povidone, microcrystalline cellulose.

Sugar free

WHAT PENTASA® 500 mg TABLETS ARE USED FOR

PENTASA® 500 mg tablets are used to treat mild to moderate attacks of ulcerative colitis and to help maintain freedom from further attacks. Ulcerative colitis is a disease 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 agent, chemically similar to aspirin, and is thought to work by reducing inflammation in the bowel.

BEFORE YOU TAKE PENTASA® 500 mg TABLETS

Do not use PENTASA® 500 mg TABLETS

- If you are allergic to mesalazine or any of the other ingredients of **PENTASA® 500 mg** tablets or aspirin-like medicines (see “What **PENTASA® 500 mg TABLETS** contain”).
- In children less than 6 years of age. Safety and efficacy has not been established.
- If you have a severe kidney or liver problem.

Take special care with PENTASA® 500 mg TABLETS

- If you have mild kidney or mild liver problems.
- If you have a history of lung disease.
- if you are on medication that may affect your kidney function e.g. non-steroidal anti-inflammatory medicine (NSAIDs) such as aspirin
- if you are allergic to sulphasalazine (due to the risk of allergy to salicylates)

Your doctor will draw blood and test your liver and kidney function before and during treatment with **PENTASA® 500 mg** tablets.

If you are about to start any new treatment or medication, remind your doctor, dentist and pharmacist that you are taking **PENTASA® 500 mg** tablets.

Caution is advised during the use of **PENTASA® 500 mg** tablets in the elderly.

Pregnancy and breastfeeding

Pregnancy

The use of **PENTASA® 500 mg** tablets by women, who are pregnant, is not recommended.

Breastfeeding

Blood disorders have been reported in newborns of mothers being treated with **PENTASA® 500 mg** tablets.

If you are taking **PENTASA®** tablets, you should not breastfeed your baby

The newborn may develop allergic reactions after breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **PENTASA® 500 mg** tablets.

Driving and using machines

PENTASA® 500 mg tablets are not expected to affect your ability to drive a car or operate machinery.

Using other medicines with PENTASA® 500 mg tablets.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **PENTASA® 500 mg** tablets with these medicines may cause undesirable interactions.

Tell your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop. Please consult your doctor, pharmacist or other healthcare professional for advice.

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
- mercaptopurine, used to treat leukaemia
- thioguanine, used to treat leukaemia
- warfarin, a blood thinner used to reduce the formation of blood clots.

HOW TO TAKE PENTASA® 500 mg TABLETS

Do not share **PENTASA® 500 mg** tablets with any other person.

Always take **PENTASA® 500 mg** tablets exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

PENTASA® 500 mg tablets must not be chewed or crushed. To help you swallow the tablets, you may disperse them in a small quantity of cold water (approximately 50ml). Stir and drink immediately.

The dose and directions of **PENTASA® 500 mg** tablets will be different for different patients and may depend on other medicines also being taken.

How much to take

Use as directed by your doctor.

Do not stop using **PENTASA® 500 mg** tablets or lower the dosage without checking with your doctor first. If you stop using it suddenly, your condition may worsen.

Adults

To treat an attack of colitis, your doctor will prescribe a dose of up to 4 g mesalazine a day administered as eight tablets of **PENTASA® 500 mg**, once a day or in divided doses.

To help maintain freedom from further attacks, your doctor will usually prescribe 2 g mesalazine a day administered as four tablets of **PENTASA® 500 mg** 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 up to 40 kg of body weight and the normal adult dose to children above 40 kg of body weight. The total dose should not exceed 2 g/day (recommended adult dose).

How long to take it

Your doctor will tell you how long your treatment with **PENTASA® 500 mg** tablets will last.

Do not stop treatment early because 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.

If you have the impression that the effect of **PENTASA® 500 mg** tablets is too strong or too weak, tell your doctor or pharmacist.

If you take more PENTASA® 500 mg tablets than you should

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

If you forget to take your PENTASA® 500 mg tablets

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.

Do not take a double dose to make up for a missed dose

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.

POSSIBLE SIDE EFFECTS

PENTASA® 500 mg tablets may have side effects.

Not all side effects reported for **PENTASA® 500 mg** tablets are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Allergic reactions may occur and are very serious.

If you notice any of the following, tell your doctor immediately or go to the emergency room 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.
- Rash with severe blisters and bleeding of the eyes, mouth, lips, nose and genitals.

Tell your doctor or pharmacist if you notice any of the following more common side effects and they worry you:

- headache
- diarrhoea
- abdominal or stomach pain
- nausea or vomiting
- rash

Tell your doctor as soon as possible if you notice any of the following other serious side effects:

- bruising easily, unusual bleeding (e.g. nosebleeds), or frequent signs of infection such as fever, chills, sore throat and mouth ulcers
- muscle aches and pains

- painful joints
- chest pain, sometimes spreading to the neck and shoulders, or with fever
- hair loss (reversible)
- numbness, tingling or weakness of the arms and legs
- yellowing of the skin or eyes, dark coloured urine
- dizziness

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

STORAGE AND DISPOSAL OF PENTASA® 500 mg TABLETS

- STORE ALL MEDICINES OUT OF REACH OF CHILDREN
- Store at or below 25 °C in the original package. Protect from light. Do not freeze.
- Do not use after the expiry date stated on the carton
- Please return expired medicine or partially used medicine to your pharmacist for safe disposal.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

PRESENTATION OF PENTASA® 500 mg TABLETS

Pack sizes of 100 tablets in double aluminium foil blisters, each strip containing 10 tablets; packed in an outer carton.

IDENTIFICATION OF PENTASA® 500 mg TABLETS

White-grey to pale-brown, speckled round tablets.

Breakmark and embossing: 500 mg on one side, PENTASA on the other side.

REGISTRATION NUMBER

33/11/0088

NAME AND ADDRESS OF REGISTRATION HOLDER

Ferring (Pty) Ltd

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DATE OF PUBLICATION

Date on the registration certificate: 17 May 2001

Date of most recently revised package insert as approved by council: 02 June 2017