

Package leaflet: Information for the user

PENTASA® 10 mg/ml Rectal Suspension

Mesalazine

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4

What is in this leaflet:

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

1. WHAT PENTASA RECTAL SUSPENSION IS AND WHAT IT IS USED FOR

The name of this medicine is PENTASA 10 mg/ml Rectal Suspension. PENTASA Rectal Suspension contains mesalazine 1 g as the active ingredient in 100 mls of liquid. Mesalazine belongs to a group of medicines called salicylates.

PENTASA Rectal Suspension is used to treat ulcerative colitis affecting the last part of the colon and rectum (back passage).

PENTASA Rectal Suspension acts locally to reduce the inflammation and help relieve or stop the pain.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE PENTASA RECTAL SUSPENSION

Do not use PENTASA Rectal Suspension:

- if you are **allergic (hypersensitive)** to **mesalazine** or any of the other ingredients of this medicine (listed in Section 6)
- if you are **allergic** to any other salicylates, e.g. aspirin
- if you have **severe liver and/or kidney** problems

Warnings and precautions

Talk to your doctor or pharmacist before taking PENTASA Rectal Suspension.

You should consult your doctor before using this medicine:

- if you experience any unexplained bleeding, bruising, skin rashes, fever or sore throat while using this medicine, stop using this medicine and seek medical advice as soon as possible
- if you currently have or have previously had liver or kidney disease
- if you are on any medication that may affect kidney function e.g. azathioprine
- if you ever had an allergy to a medication called sulphasalazine
- if you have lung problems, in particular asthma

- if you suddenly develop cramps, abdominal pain, fever, severe headache and rash. In such circumstances you should stop taking PENTASA immediately
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using mesalazine.

If you suffer from kidney problems you will require regular check ups by your doctor.

- Kidney stones may develop with use of mesalazine. Symptoms may include pain in sides of abdomen and blood in urine. Take care to drink sufficient amount of liquid during treatment with PENTASA Rectal Suspension.

Mesalazine 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.

Take special care with mesalazine:

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 mesalazine treatment. Stop using PENTASA Rectal Suspension and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Other medicines and PENTASA Rectal Suspension

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

- **azathioprine** (used after transplantations or to treat auto-immune diseases)
- **6-mercaptopurine or thioguanine** (chemotherapy, used to treat leukaemia)
- certain agents that inhibit blood clotting (medicines for thrombosis or to thin your blood).

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

There is limited experience with the use of mesalazine during pregnancy and breast-feeding. Blood disorders have been reported in newborns of mothers being treated with this medicine. The newborn may develop allergic reactions after breast-feeding, e.g. diarrhoea. If the newborn develops diarrhoea, breast-feeding should be discontinued.

Driving and using machines

This medicine is not known to affect the ability to drive and/or use machines.

3. HOW TO USE PENTASA RECTAL SUSPENSION

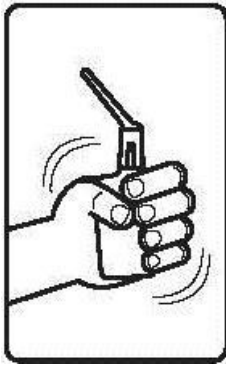
Always use PENTASA Rectal Suspension exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The rectal suspension should be used in the back passage (rectum) only. Usually your doctor will ask you to use one rectal suspension at bedtime.

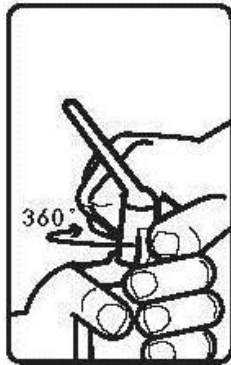
Adults

Usually your doctor will tell you to use one rectal suspension at bedtime.

How to use the Rectal Suspension



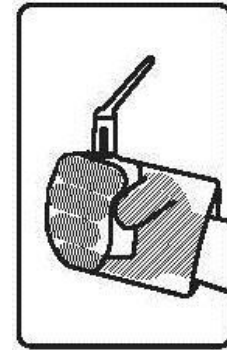
1. Immediately before use take the rectal suspension bottle out of the aluminium foil pack and shake it well.



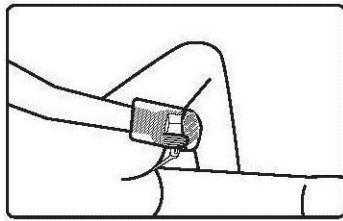
2. To break the seal twist the nozzle clockwise one full turn (the nozzle should then be in the same direction as before turning).



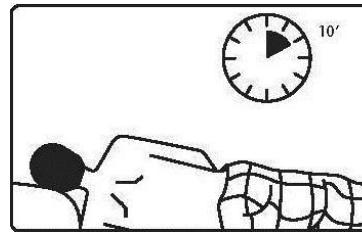
3. Put your hand in one of the plastic disposal bags provided in the pack.



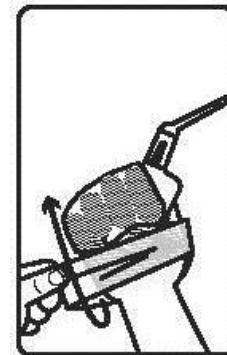
4. Hold the container as shown in the picture.



5. To administer the rectal suspension, lie on your left side with the left leg straight and the right leg bent forward for balance. Carefully insert the applicator tip into the rectum. Maintain sufficient steady hand pressure while dispersing the bottle content. The bottle content should be applied within max. 30-40 seconds.



7. The rectal suspension should be retained in the bowel. Remain relaxed in the administration position for 5-10 minutes or until the urge to pass the rectal suspension has disappeared.



8. Roll the plastic disposal bag over the empty bottle. Discard it and wash your hands

The rectal suspension may colour the linen and toilet.

If you use more PENTASA Rectal Suspension than you should

If you accidentally use too much PENTASA Rectal Suspension, you should go to your nearest emergency department or contact your doctor immediately. Take the pack and any remaining bottles with you.

If you forget to use PENTASA Rectal Suspension

If you forget to use a dose of PENTASA Rectal Suspension, use the next dose in the morning if it is convenient. Otherwise, use one as usual the next night. Do not use a double dose to make up for the forgotten one.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using PENTASA Rectal Suspension and seek medical attention immediately if you notice any of the following symptoms:

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.

There have been very few reports of a severe allergic reaction (including severe skin erosions that may affect the skin as the protective barrier of the body). The allergic reaction might lead to swelling of the face and neck and/or difficulty in breathing or swallowing. If this happens contact your doctor or nearest casualty department immediately.

The following common side effects affect between 1 and 10 of every 100 patients treated:

- diarrhoea
- abdominal pain
- nausea
- vomiting
- headache
- rash
- flatulence (passing wind)
- anal discomfort and irritation at the application site, itching and feeling of incomplete defecation (tenesmus)

The following rare side effects affect between 1 and 10 of every 10,000 patients treated:

- inflammation of some areas of the heart (myocarditis and pericarditis) which can cause shortness of breath and chest pain or palpitations (rapid or irregular heart beats)
- inflammation of the pancreas (symptoms include back and/or stomach pain)
- increased amylase (enzyme that helps digest carbohydrates)
- dizziness
- increased sensitivity of your skin to sun and ultraviolet light (photosensitivity)

The following very rare side effects affect less than 1 of 10,000 patients treated:

- anaemia and other blood disorders (decrease in the numbers of certain blood cells, which can cause unexplained bleeding, bruising, fever or sore throat)
- liver disorders (symptoms include jaundice (yellowing of the skin and/or eyes) and/or pale bowel motions)
- kidney disorders (symptoms include blood in the urine and/or oedema (swelling due to build up of fluid))
- peripheral neuropathy (a condition affecting the nerves of the hands and feet, symptoms include tingling and numbness)
- allergic and fibrotic lung reactions, inflammation of the lining of the lungs or lung scarring (symptoms include coughing, bronchospasm, chest discomfort or pain on breathing, breathing difficulties, bloody and/or excessive phlegm)
- pancolitis (a kind of inflammatory bowel disorder (IBD) that affects the entire internal lining of the large bowel)
- hair loss (this is reversible)
- muscle or joint pain
- inflammation which can affect different parts of the body such as joints, skin, kidneys, heart etc. (symptoms include painful joints, fatigue, fever, abnormal or unexplained bleeding (e.g. nose bleeds), bruising, purple discoloration of the skin (including severe skin erosions and severe blistering that may affect the skin as the protective barrier of the body))
- semen with a low concentration of sperm (oligospermia) (this is reversible)
- severe diarrhoea and abdominal pain because of an allergic reaction to this medicine within the bowel
- allergic reactions and fever may occasionally occur.

Not known (frequency cannot be estimated from the available data):

- kidney stones and associated kidney pain (see also section 2)
- change in urine colour.

Reporting of side effects

If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PENTASA RECTAL SUSPENSION

Keep this medicine out of the sight and reach of children.

Store below 25°C. Do not freeze. Store in the original package in order to protect from light. Use immediately after opening the individual foil pack.

Do not use this medicine after the expiry date which is stated on the bottle label and carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What PENTASA Rectal Suspension contains

Each bottle of PENTASA Rectal Suspension contains 1g of the active ingredient, mesalazine in 100 mls of liquid. The mesalazine settles out as a separate layer. The other ingredients are disodium edetate, sodium metabisulphite (E223), sodium acetate, purified water and hydrochloric acid to adjust the acidity of the product to values which are suitable for administration.

What PENTASA Rectal Suspension looks like and the contents of the pack

PENTASA Rectal Suspension is a white to faint yellow suspension presented in a polyethylene bottle. Each carton contains 7 individually foil-wrapped rectal suspension bottles and 7 plastic bags for disposal of the empty rectal suspension bottle after use.

Marketing Authorisation Holder

Ferring Ireland Limited, United Drug House, Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland.

Manufacturer

Ferring Léčiva, a.s., K Rybníku 475, 252 42 Jesenice, Czech Republic.

This leaflet was last revised in 01/2023.

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