Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What Pentasa is and what it is used for
2. Before you use Pentasa
3. How to use Pentasa
4. Possible side effects
5. How to store Pentasa
6. Further Information

1. WHAT PENTASA IS AND WHAT IT IS USED FOR

The name of this medicine is Pentasa Mesalazine Enema in the form of a suspension. Each bottle contains mesalazine 1g in 100ml of liquid as the active ingredient. Mesalazine belongs to a group of medicines called salicylates.

Pentasa is used to treat inflammation in the gut caused by conditions such as active ulcerative colitis where it is affecting the last part of the colon and rectum (back passage).

The enema releases the active ingredient which then acts locally to reduce the inflammation and help relieve or stop the pain.

2. BEFORE YOU USE PENTASA

Do Not use Pentasa if you:
• are allergic to mesalazine or any of the other ingredients in Pentasa (see section 6)
• are allergic to any other salicylates e.g. Aspirin
• have severe liver or kidney problems

Pentasa is not suitable for use in children.

Take special care with Pentasa
You should consult your doctor before using these enemas if:
• you currently have, or have previously had liver or kidney disease
• you are on any medication that may affect kidney function e.g. azathioprine
• you have ever had an allergy to a medication called sulphasalazine
• If you have lung problems, in particular asthma.

While you are using Pentasa your doctor may occasionally want to check your kidney function.

If you suddenly develop abdominal cramps, abdominal pain, fever, severe headache and rash, stop using this medicine and seek medical advice immediately.

You should make sure that you don’t become dehydrated, while you are using this medicine. This can occur after severe or prolonged attacks of vomiting and/or diarrhoea, high fever or heavy sweating. If this does occur, you should speak to a doctor or pharmacist for advice as soon as possible.

Using other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any of the following:
• Azathioprine, 6-mercaptopurine or thioguanine
• Certain agents that inhibit blood clotting (medicines for thrombosis or to thin your blood, e.g. warfarin)

Pregnancy and Breast-feeding
If you are pregnant, planning to become pregnant or are breast-feeding you should speak to your doctor or pharmacist for advice before taking this medicine.

There is limited experience with the use of mesalazine during pregnancy and breast-feeding. The newborn may develop allergic reactions after breast-feeding, e.g. diarrhoea. If the newborn develops diarrhoea, breast-feeding should be discontinued.

3. HOW TO USE PENTASA

For Adult use only, not recommended in children.

Always use Pentasa exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Usually your doctor will ask you to use one enema at bedtime.

How to use the enema
1. Immediately before use take the enema 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 enema, 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.

6. Once the bottle is empty, withdraw the tip with the bottle still compressed

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

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

Please note: Pentasa Mesalazine may cause permanent staining on contact with clothing or fabrics.
If you use more Pentasa than you should
If you accidentally use too much, you should go to your nearest emergency department or contact your doctor immediately. Take the carton with you.

If you forget to use Pentasa
If you forget to use a dose, 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, Pentasa can cause side effects although not everyone gets them.

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

STOP taking Pentasa if you notice:
• Itching, skin rashes, swelling of the face, lips or throat, difficulty in breathing or wheeziness (signs of an allergic reaction).
• Skin disorder due to an allergic reaction or infection (Erythema multifforme or Stevens-Johnson syndrome). Symptoms include severe rash, blisters or red splotches on the skin.
• Unexplained bleeding, bruising, skin rashes, fever or sore throat (signs of blood disorder).
• Change in colour or amount of urine produced (signs of kidney problems).
• Chest pain, an increase in heartbeat or excess tiredness (signs of heart problems).
• Inflammation of the liver or liver failure, symptoms include yellowing of the eyes and/or skin (Jaundice), dark urine, stomach pain, fever, feeling tired or nausea.
• Inflammation of the pancreas, symptoms include back and/or stomach pain, fever, nausea and vomiting.
• Ulcerative colitis involving the entire large intestine.

If you experience any of the above side effects you should contact your doctor or go to the nearest hospital emergency department immediately.

Common side effects
(may affect up to 1 in 10 people)
• rash with or without itching

Rare side effects
(may affect up to 1 in 1,000 people)
• vomiting
• stomach pain
• nausea
diarrhoea
• headache
• inflammation of the heart or area surrounding the heart
• dizziness
• flatulence (passing wind)
• raised level of a pancreatic enzyme
• Increased sensitivity of your skin to sun and ultraviolet light (photosensitivity).

Very rare side effects
(may affect up to 1 in 10,000 people)
• raised liver enzymes
• hair loss (reversible)
• joint and muscle pain
• allergic reactions and fever
• lupus erythematosis (an auto-immune disorder effecting the skin)
• skin rash or blisters e.g. Erythema Multiforme or Steven-Johnson syndrome
• semen with a low concentration of sperm (oligospermia) (this is reversible)
• blood disorders (e.g. low levels of red blood cells)
• tingling or numbness in the hands and feet
• allergic and fibrotic lung reactions (including breathing problems)
• changes in kidney function or kidney failure
• inflammation of the pancreas

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PENTASA
Do not store above 25°C.
Keep the foil packed bottles in the outer carton in order to protect them from light.
Do not use after the expiry date detailed on the pack.
Keep out of sight and reach of children.
Return any old or unused medicines to your pharmacist for disposal.

6. FURTHER INFORMATION

What Pentasa contains
Each bottle contains 1g of the active ingredient, mesalazine in 100ml of liquid. The mesalazine settles out as a separate layer. It also contains the following inactive ingredients: disodium edetate, sodium metabisulphite, sodium acetate, hydrochloric acid, purified water.

What Pentasa looks like and the contents of the pack
The enema is a colourless to faint yellow suspension presented in a polythene bottle. Each pack contains 7 individually foil-wrapped enema bottles and 7 polythene bags for disposal of the empty enema bottle after use.

Marketing Authorisation Holder
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This leaflet was last revised in January 2018.
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