

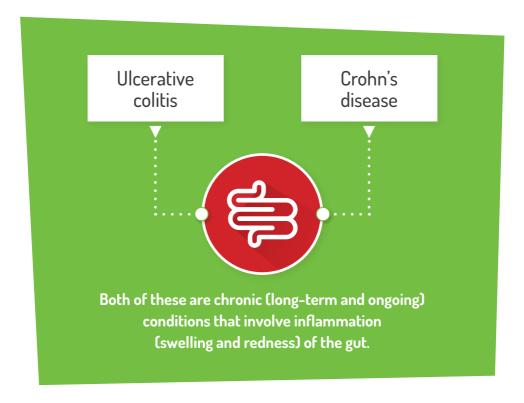


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What is inflammatory bowel disease?

Inflammatory bowel disease (commonly called IBD) is a term mainly used to describe two conditions:



People of any age can develop IBD, but it is usually diagnosed between the ages of 15 and 40. It is unclear what causes the condition but a number of different things are thought to be involved, including genetics (e.g. if you have a close relative with the condition) and a problem with your immune system.

IBD affects more than 300,000 people in the UK.

What is ulcerative colitis?

Ulcerative colitis causes inflammation and ulcers (open sores) to appear on the lining of the colon (large intestine) and rectum. Symptoms vary from person to person and range from mild to severe. They may change over time, with periods of good health where you will have few or no symptoms, this is known as remission. These periods may alternate with times when your symptoms are more active, commonly referred to as 'flare ups'.

What are the main types of ulcerative colitis?

Ulcerative colitis is generally categorised according to how much of the colon is affected. The diagram shows the four main types:



What symptoms can I expect to experience?

The main symptoms include:

- > Diarrhoea

- > Abdominal pain
- > Extreme tiredness
- > Feeling generally unwell
- > Loss of appetite and weight

How is ulcerative colitis treated?

Ulcerative colitis is managed with medication. Treatment will depend on how severe your symptoms are and the choices you make with your doctor. Drugs used to help control IBD include anti-inflammatory drugs (such as 5-ASAs and steroids), immunosuppressants (such as azathioprine, methotrexate and cyclosporin) and biological drugs (like infliximab and adalimumab).

Initially, the aim of treatment is to reduce inflammation in your gut to provide relief from the symptoms you may be experiencing. Once your disease is under control, your doctor may continue to prescribe drugs to prevent your symptoms from coming back.

In some cases, if your symptoms are severe and medication is not effective, surgery may be needed.



Why have I been prescribed PENTASA?

You have been prescribed PENTASA for the treatment of your ulcerative colitis. It contains a substance called mesalazine, which is an anti-inflammatory.

PENTASA reduces inflammation in the gut and may be used when your colitis symptoms are flaring (when your disease is active) and also to prevent them from returning (this is also known as maintenance treatment).



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Why is it important to take my medication?

People with life-long diseases, such as ulcerative colitis, may not always take their medicines as instructed by their doctor. This may be due to fear of possible side effects, feeling much better and therefore thinking the medicine is no longer necessary or through forgetting to take their medicine.

When your symptoms are bad, and you can feel the effects of the drug, it may make remembering to take your medicine easier. However, when you feel better, it may make remembering to take your medicine more difficult. You may also be tempted to stop taking your medicine or feel disheartened about having to take your pills every day.

These are all understandable feelings. However, IBD cannot be cured but can be managed and many studies have shown that continuing to take your medicine, even when you feel well, helps to reduce the chance of flare ups. Repeated flare ups can increase the risk of irreversible damage to your intestines and may lead to complications, such as your colon becoming stretched and enlarged. Continuing to take your medication may also mean that you are less likely to need to take more or stronger drugs in the future.

Please contact your healthcare professional if you experience difficulties.

Helpful tips for remembering to take your PENTASA



Take your medicine at the same time each day and try making this a part of your daily routine

> If you are prone to forgetting things, like taking your tablets, try taking them with a set meal like breakfast, or after brushing your teeth in the morning



Place your tablets in a pill dispenser with the days of the week written on



Put your medication in the same, safe place every day so that you know where it is



Set alarm reminders or download the PENTASA Diary App to do it for you – For more information on the web app please see overleaf



Discuss any concerns you may have about your treatment with your IBD team

> They will understand your concerns and may be able to offer alternatives

Introducing the PENTASA Diary

The PENTASA Diary is a free web app designed to help keep you in remission by reminding you to take your PENTASA at the right time and at the right dosage to fit in with your daily routine.

The PENTASA Diary web app includes:

- > Daily text alerts, reminding you when to take your PENTASA medicine
- > Contact details for helpful support, including your IBD nurse or IBD helpline, GP and Crohn's & Colitis UK helpline
- > Useful information about your condition and treatment

Sign up for daily text reminders by visiting the PENTASA Diary web app at: www.pentasadiary.co.uk



What should I know before taking PENTASA?

As with all medications, PENTASA may cause side effects, although not everybody gets them. Understanding the possible side effects may help you recognise when you might need to seek help.

The most common side effects of PENTASA include:



Nausea, vomiting, diarrhoea, abdominal pain



Rash



Headache

The Patient Information Leaflet in the PENTASA medication pack provides the full list of potential side effects.

Stop taking PENTASA if you notice signs of the following:



Allergic reaction including itching, rashes, swelling of the face, lips and throat, difficulty breathing or wheeziness



Blood disorder including unexplained bleeding, bruising, rashes, fever or sore throat



Kidney problems such as a change in the colour or amount of urine produced

If you experience any of the above side effects you should contact your IBD team or doctor.

Who should not take PENTASA?

You should not take PENTASA if:

- > You have an allergy to other medicines containing salicylate e.g. aspirin
- > You are a child under the age of 15 (tablets) or you are a child under the age of 6 (sachets)
- > You have severe liver and/or kidney problems
- > You are allergic to any of the ingredients of PENTASA

If you are unsure about any of the above then speak to your doctor.

If you are pregnant, planning to become pregnant or are breastfeeding, speak to your doctor or pharmacist about taking PENTASA as they will need to decide if this medicine is suitable.

What if I forget to take PENTASA or take too much?

If you forget to take your PENTASA dose, take the next dose as soon as you remember, unless it is less than 3 hours until your next dose. It is important that you do not take a double dose to make up for the one that was forgotten.

If you accidentally take too much medication, you should go to your nearest emergency department or contact your doctor immediately. Ensure you take the pack and any remaining medication with you.

If you have any questions then ask your doctor.

More information about PENTASA

PENTASA is available in a range of formulations for both oral and rectal administration.

- > Oral formulations include: granules (sachets) and tablets
- > Rectal preparations include: suppositories and liquid enemas

PENTASA oral formulations

PENTASA sachets are available in three different dose strengths:



 PENTASA sachets can be added to a yoghurt pot or drink to aid with swallowing and should be consumed immediately



PENTASA tablets are available in two dose strengths:



1g tablets

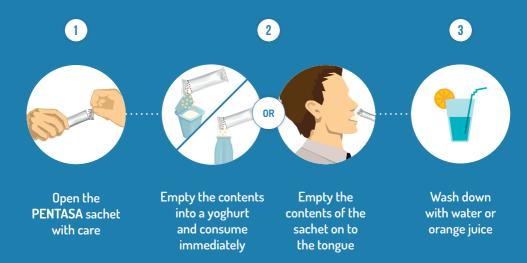
500 mg tablets

- > PENTASA tablets can be dispersed in water to help with swallowing
- > PENTASA does not need to be taken with food, so it can be taken at anytime of the day to help fit in with your daily routine
- > PENTASA tablets and sachets may be taken once daily



How do I take oral PENTASA formulations?

PENTASA sachets:



PENTASA tablets:



It is important to remember to take your medication as advised by your doctor. Failing to do so means you may not receive the full therapeutic benefits of the medication.



PENTASA rectal preparations

PENTASA rectal preparations are available in two administration routes:



How do I take rectal PENTASA formulations?

How to use the enema

- 1. Immediately before use take the enema bottle out of the aluminium foil pack and shake 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 disposal bags provided in the pack.
- 4. Wrap this hand around the enema bottle.
- **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. The bottle content should be applied within a maximum of 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 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.

How to insert the suppository

You should make sure that you empty your bowels before inserting the suppository.

- 1. Tear along the perforation to remove one suppository blister from a blister strip.
- 2. Put a protector on the finger with which you will insert the suppository.
- **3.** Remove the suppository from the blister before insertion. This is done by pushing the suppository through the printed foil.
- **4**. Insertion may be made easier if you moisten the suppository with water first.
- **5**. Insert the suppository gently and fully into the rectum. It may help to lie down on one side and raise the other knee.
- **6.** Remain still for a few minutes after insertion to help keep the suppository in place. If it comes out within 10 minutes, a new one should be inserted.
- **7.** Dispose of the empty blister and used finger protector safely and wash your hands.

It is important to remember to take your medication as advised by your doctor. Failing to do so means you may not receive the full therapeutic benefits of the medication.



Frequently Asked Questions

Can I chew PENTASA tablets?

The tablets should be taken by mouth whole, they should **not** be crushed or chewed. If you have difficulty swallowing the tablets you can disperse them in a small quantity of cold water (approximately 50 ml) then stir and drink immediately.

Can PENTASA tablets/granules (sachets) be taken after food?

Yes, they can. The movement of PENTASA through the gut and its release is not affected if taken with or without food.

Does PENTASA react with other medications?

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

This is especially important if you are taking 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)

Is PENTASA suitable for vegetarians?

The active ingredient for both oral and rectal PENTASA preparations, and their coatings, are not derived from animal sources. Therefore, PENTASA is suitable for vegetarians.

Is PENTASA lactose free?

Yes. None of the PENTASA formulations (enema, sachets, suppositories, tablets) contain lactose.

Is PENTASA gluten free?

Yes. None of the PENTASA formulations (enema, sachets, suppositories, tablets) contain gluten.

Does PENTASA contain latex?

Latex is not used in any of the products or in their packaging. However, the finger cots for the suppositories are made of latex.

If you have any further questions please consult your doctor or refer to the Patient Information Leaflet that can be found in your PENTASA medication pack.



My IBD Team contact number is:

My IBD Team email address is:

Useful places for further information:

PENTASA diary: www.pentasadiary.co.uk

Crohn's & Colitis UK: www.crohnsandcolitis.org.uk

Crohn's & Colitis Foundation: www.crohnscolitisfoundation.org

My Crohn's and Colitis Team: www.mycrohnsandcolitisteam.com

Traveling abroad: s3-eu-west-1.amazonaws.com/files.

crohnsandcolitis.org.uk/Publications/travel-and-IBD.pdf

CICRA: www.cicra.org

Ferring: www.ferring.co.uk/en/home

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 the package leaflet.

You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard

By reporting side effects, you can help provide more information on the safety of this medicine.

This information leaflet is not intended to be a substitute for medical advice. You should consult your doctor for specific advice about your condition. You should also read through the Patient Information Leaflet, which can be found in your PENTASA medication pack.

