

PACKAGE LEAFLET: INFORMATION FOR THE USER

Mezavant® XL 1200mg gastro-resistant, prolonged release tablets (mesalazine)

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.
- The name of this medicine is Mezavant XL 1200mg gastro-resistant, prolonged release tablets but will be referred to as Mezavant XL throughout the remainder of this leaflet.

In this leaflet:

- 1) What Mezavant XL is and what it is used for
- 2) Before you take Mezavant XL
- 3) How to take Mezavant XL
- 4) Possible side effects
- 5) How to store Mezavant XL
- 6) Further information

1) WHAT MEZAVANT XL IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group: Aminosalicylic acid and similar agents.

Mezavant XL gastro-resistant, prolonged release tablets contain mesalazine, which is an anti-inflammatory drug for the treatment of ulcerative colitis.

Ulcerative colitis is a disease of the colon (large bowel) and rectum (back passage), where the lining of the gut becomes red and swollen (inflamed) resulting in symptoms of frequent and bloody stools together with stomach cramps.

When given for an acute episode of ulcerative colitis, Mezavant XL acts through the entire colon and rectum to treat the inflammation and reduce symptoms. The tablets can also be taken to help prevent reoccurrence of ulcerative colitis.

2) BEFORE YOU TAKE MEZAVANT XL

Do not take Mezavant XL

- If you are allergic (hypersensitive) to a family of drugs known as salicylates (which include aspirin)
- If you are allergic (hypersensitive) to mesalazine or any of the other ingredients of Mezavant XL listed in section 6 of this leaflet
- If you have severe kidney or severe liver problems

Take special care with Mezavant XL: Before treatment with Mezavant XL, tell your doctor

- If you have any kidney or liver problems
- If you have previously had inflammation of the heart (which may be the result of an infection in the heart)
- If you have had a previous allergic reaction to sulphasalazine (another medicine used to treat ulcerative colitis)
- If you have narrowing or blockage of the stomach or the gut
- If you have lung problems

Using other medicines

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

- Mesalazine or sulphasalazine (taken for treatment of ulcerative colitis)
- Non-steroidal anti-inflammatory drugs (for example medicines containing aspirin, ibuprofen or diclofenac)
- Azathioprine or 6-mercaptopurine (known as “immunosuppressant” medicines which reduce the activity of your body’s immune system).
- Coumarin-type anticoagulants (medicines which increase the time it takes for your blood to clot) e.g. warfarin

Taking Mezavant XL with food and drink

Mezavant XL should be taken with food at the same time each day. The tablets should be swallowed whole and must not be crushed or chewed.

Pregnancy and breast-feeding

Since mesalazine crosses the placenta in pregnancy and is excreted in breast milk in small quantities, due care should be taken if using Mezavant XL in pregnancy or whilst breast-feeding.

If you are pregnant, think you might be pregnant or are breast-feeding you should ask your doctor for advice about taking Mezavant XL.

Driving and using machines

Mezavant XL is unlikely to have any effect on your ability to drive or use machines.

3) HOW TO TAKE MEZAVANT XL

Always take Mezavant XL as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual daily dose for adults is 2.4g to 4.8g (two to four tablets) taken once a day for an acute episode of ulcerative colitis. If you are taking the highest daily dose of 4.8g/day, you should be evaluated after 8 weeks treatment. Once your symptoms have cleared and to help prevent reoccurrence of another episode, your doctor should direct you to take 2.4g (two tablets) once a day.

Remember to take your tablets at the same time each day with food. The tablets should be swallowed whole and must not be crushed or chewed.

Mezavant XL is not recommended to be given to children under 18 years of age due to lack of data on safety and efficacy.

If you take more Mezavant XL than you should

If you take too much Mezavant XL you may have one or more of the following symptoms: tinnitus (ringing in ears), dizziness, headache, confusion, drowsiness, shortness of breath, excess loss of water (associated with sweating, diarrhoea and vomiting), low blood sugar (which can cause light-headedness), rapid breathing, changes in the blood chemistry and increased body temperature.

If you do take too many tablets, contact your doctor, pharmacist or hospital casualty department straight away. Take your tablet pack with you.

If you forget to take Mezavant XL

It is important to take your Mezavant XL tablets every day, even when you don't have any symptoms of ulcerative colitis. Always finish the prescribed course.

If you forget to take your tablets then take them as usual the next day. Do not take a double dose to make up for a forgotten tablet.

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

4) POSSIBLE SIDE EFFECTS

Like all medicines, Mezavant XL can cause side effects, although not everybody gets them.

Common side effects, occurring in less than 1 in 10 patients, are headache, changes in blood pressure, flatulence (passing wind), nausea (feeling sick), bloated or painful stomach, diarrhoea, indigestion, vomiting (being sick), abnormal liver function test, itching, rash, muscle and joint pain, back pain, weakness and fever (high temperature).

Uncommon side effects, seen in less than 1 in 100 patients are: a reduction in blood platelets which increases the risk of bleeding and bruising; dizziness; feeling sleepy or tired; trembling or shaking; ear pain; racing heartbeat; changes in blood pressure; an inflamed pancreas or colon (associated with pain in upper abdomen and back and feeling sick); rectal polyp (a non-cancerous growth in the back passage causing symptoms such as constipation and bleeding); acne; hair loss; itchy skin with or without a rash; hives; swollen face; fatigue (feeling extremely tired).

If any of the side effects become serious or persist, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Tell your doctor immediately

- If you experience symptoms such as cramping, severe stomach pain, bloody and excessive stools (diarrhoea), fever, headache or rash. These symptoms could be a sign of Acute Intolerance Syndrome which can happen during an acute episode of ulcerative colitis. This is a serious condition which occurs rarely, but means your treatment would have to be stopped immediately
- If you develop unexplained bruising (without injury), rash, anaemia (feeling tired, weak and looking pale, especially on lips, nails and inside of eyelids), fever (high temperature), sore throat or unusual bleeding (e.g. nose bleeds)
- If you develop allergic swelling of tongue, lips and around eyes

5) HOW TO STORE MEZAVANT XL

- Keep out of the sight and reach of children
- Do not store above 25°C
- Store in the original package in order to protect from moisture.
- Do not use Mezavant XL after the expiry date which is stated on the box
- If your tablets become discoloured or show any sign of deterioration, return them to your pharmacist.
- Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines you no longer require or medicines that have expired. These measures will help to protect the environment.

6) FURTHER INFORMATION

What Mezavant XL contains

The active substance is mesalazine. Each tablet contains 1200mg mesalazine.

The other ingredients are:

Tablet core: Carmellose sodium, Carnauba Wax, Stearic Acid, Colloidal Hydrated Silica, Sodium Starch Glycolate, Talc, Magnesium Stearate
Film-coating: Talc, Methacrylic Acid Copolymer Type A, Methacrylic Acid Copolymer Type B, Triethylcitrate E1505, Titanium Dioxide (E171), Red Ferric Oxide (E172), Macroqol 6000.

What Mezavant XL looks like and contents of the pack

Mezavant XL gastro-resistant, prolonged release tablets are red-brown, ellipsoidal, film-coated tablet, debossed on one side with S476 and plain on the reverse.

Mezavant XL is supplied in foil blister strips which are contained in a cardboard box.

Mezavant XL is available in packs of 60 tablets.

This medicine is manufactured by Cosmo S.p.A. Via C. Colombo 1, 20020 Lainate-Milan, Italy. Procured from within the EU by the Parallel Product Authorisation Holder: MPT Pharma Ltd., Westgate Business Park, Unit 5-7 Tintagel Way, Aldridge, Walsall WS9 8ER, UK.

Repackaged by MPT Pharma Ltd., Westgate Business Park, Unit 5-7
Tintagel Way, Aldridge, Walsall WS9 8ER, UK.

Leaflet date 27/06/2013

Leaflet code xxxxxxxxxx

POM

Mezavant XL 1200mg gastro-resistant, prolonged release tablets

PPA: 1825/002/001

Mezavant[®] is a registered trade mark of
XX