Package leaflet: Information for the user

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

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- 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 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 Mezavant XL is and what it is used for

Pharmacotherapeutic group: Aminosalicylic acid and similar agents.

Mezavant XL gastro-resistant, prolonged release tablets contain the active substance 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 reccurrence of ulcerative colitis.

2. What you need to know 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 this medicine (listed in section 6 of this leaflet)
- If you have severe kidney or severe liver problems

Warnings and precautions

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.

Talk to your doctor before using Mezavant XL

- 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 ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using Mezavant
- 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

Before and periodically during treatment with Mezavant XL, your doctor may take samples of your urine and blood to check that your kidneys and liver are working well and that your blood is healthy.

Kidney stones may develop with the use of Mezavant XL. Symptoms may include pain in the sides of the abdomen and blood in the urine. Take care to drink a sufficient amount of liquid during treatment with Mezavant XL.

Serious skin reactions, such as Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported in association with Mezavant treatment. Stop using Mezavant and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Children and adolescents

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

Other medicines and Mezavant XL

Studies have shown that Mezavant XL does not interfere with the following antibiotics, used to treat infections: amoxicillin, metronidazole or sulfamethoxazole.

However, Mezavant XL may interact with some other medicines. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
- 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 or other medicines known to affect how your bone marrow works (known as ‘immunosuppressant’ medicines which reduce the activity of your body’s immune system). Bone marrow is the material inside your bones that produces blood cells.
- Coumarin-type anticoagulants (medicines which increase the time it takes for your blood to clot) e.g., warfarin

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, you should only use Mezavant XL during pregnancy or whilst breast-feeding if your doctor tells you to. Adverse outcomes [including low blood counts (white blood cells, red blood cells, and platelets)] were reported in infants born to mothers who took Mezavant XL during pregnancy. Diarrhoea has been reported in breastfed infants of mothers who took Mezavant XL.

If you are pregnant or breast feeding, think you might be pregnant or are planning to have a baby, ask your doctor for advice about taking Mezavant XL.

Interference with laboratory tests

If you are undergoing urine tests, it is important to tell the doctor or nurse you are taking, or have recently taken this medicine as it can affect some results.

Driving and using machines

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

Mezavant contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per the maximum recommended dose (4 tablets), that is to say essentially 'sodium-free'.

3. How to take Mezavant XL

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for adults is 2.4 g to 4.8 g (two to four tablets) taken once a day for an acute episode of ulcerative colitis. If you are taking the highest daily dose of 4.8 g/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 2.4 g (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.

Whilst taking this medicine ensure you drink fluids to remain well hydrated especially after severe or prolonged episodes of vomiting and/or diarrhoea, high fever or heavy sweating.

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 medicine, ask your doctor or pharmacist.

4. Possible side effects

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 notice 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. These serious skin rashes can be preceded by fever and flu-like symptoms.
- If you develop allergic swelling of tongue, lips and around eyes.
- If you develop increased pressure in brain causing headache which may originate behind your eyes and worsen with eye movements, with blurred or dimmed vision, double vision, seeing light flashes, difficulty seeing to the side, and brief or permanent vision loss. These may be associated with dizziness, nausea, vomiting, ringing in ears.

Like all medicines, this medicine 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; inflammation which causes abdominal pain or diarrhoea; diarrhoea; indigestion; vomiting (being sick); abnormal liver function test; itching; rash, joint pain; back pain; weakness, fatigue (feeling extremely tired); 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; throat pain; an inflamed pancreas (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; muscle pain; hives; swollen face.

Rare side effects, seen in less than 1 in 1000 patients are: kidney failure; severe reduction in the number of white blood cells that makes infection more likely; increased sensitivity of your skin to sun and ultraviolet light (photosensitivity).

The following side effects have been reported but it is not known exactly how often they occur:
Severe reduction in blood cells which can cause weakness or bruising; low blood cell counts; allergic reaction (hypersensitivity); serious allergic reaction which causes difficulty in breathing or dizziness; serious illness with blistering of the skin (possibly leading to peeling of the skin and resulting in painful, raw areas), mouth, eyes and genitals; allergic reaction which causes skin rash, fever and inflammation of internal organs; neuropathy (abnormal or damaged nerves giving a sensation of numbness and tingling); inflammation of the heart and lining around the heart; inflammation of the lung; difficulty in breathing or wheezing; gall stones; hepatitis (inflammation of the liver giving rise to flu-like symptoms and jaundice); hepatotoxicity (liver damage that may present as abnormal liver tests); allergic swelling of tongue, lips and around eyes; skin redness; skin rash typically on face, skin sensitivity to sunlight along with joint pain, arthritis, fatigue and overall feeling sickness; kidney problems (such as inflammation and scarring of the kidney); kidney stones and associated pain (see also section 2); reversible decrease in sperm production.

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 national reporting system (see

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

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

Malta
ADR Reporting
Website:
www.medicinesauthority.gov.mt/adrportal

5. How to store Mezavant XL

- Keep this medicine out of the sight and reach of children
- Store below 25°C
- Store in the original package in order to protect from moisture
- Do not use this medicine after the expiry date which is stated on the box after "EXP". The expiry date refers to the last day of that month
- Do not throw away any medicines via waste water 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 Mezavant XL contains

The active substance is mesalazine 1200 mg.

The other ingredients are: Carmellose sodium; Carnauba Wax; Stearic Acid; Silica, Colloidal Hydrated; Sodium Starch Glycolate (Type A); Talc; Magnesium Stearate; Methacrylic Acid – Methyl Methacrylate Copolymer (1:1); Methacrylic Acid – Methyl Methacrylate Copolymer (1:2) Triethylcitrate; Titanium Dioxide (E171); Red Ferric Oxide (E172); Macrogol 6000.

What Mezavant XL looks like and contents of the pack
Mezavant XL is supplied in foil blister strips which are contained in a cardboard box. The pack contains 60 or 120 tablets. Not all pack sizes may be marketed.

The red-brown tablets are oval shaped and stamped S476.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Ireland/Malta

Takeda Pharmaceuticals International AG Ireland Branch
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This medicinal product is authorised in the Member States of the EEA under the following names:

Austria, Belgium, Cyprus, Denmark, Germany, Greece, Hungary, Luxembourg, Netherlands, Norway, Poland, Portugal, Spain and Sweden.	Mezavant
Ireland, Malta and United Kingdom	Mezavant XL

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Detailed information on this medicine is available on the web site of: www.hpra.ie (Ireland) or www.medicinesauthority.gov.mt (Malta).