

Approved patient information leaflet for MEZAVANT

SCHEDULING STATUS

S3

MEZAVANT, 1200 mg, enteric coated, prolonged-release tablet

Mesalazine

Sugar free.

Read all of this leaflet carefully before you start taking MEZAVANT

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- MEZAVANT has been prescribed only for you and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What MEZAVANT is and what it is used for

MEZAVANT is a gastro-resistant, prolonged release tablet which contains mesalazine.

MEZAVANT is used for the treatment and maintenance for the remission of ulcerative colitis.

2. What you need to know before you take MEZAVANT

Do not take MEZAVANT

- if you are allergic (hypersensitive) to a family of medicines named salicylates (which include aspirin) and non-steroidal anti-inflammatory medicines (e.g. ibuprofen).
- if you are allergic (hypersensitive) to mesalazine or any of the other ingredients of MEZAVANT (see 'What MEZAVANT contains').
- if you have severe kidney or severe liver problems.

Warnings and precautions

Take special care with MEZAVANT:

- 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 (especially asthma).
- If you experience symptoms such as stomach cramps, abdominal pain, bloody and excessive stools (diarrhoea), fever, headache or rash, contact your doctor. These symptoms could be a sign of acute intolerance syndrome, a condition with symptoms similar to those of ulcerative colitis.
- if you develop unexplained bleeding, bruising, skin discolouration, fever or a sore throat contact your doctor. MEZAVANT treatment may cause abnormality in the blood's cellular components.
- MEZAVANT may cause kidney stones. You should drink a fair amount of fluid (such as water) during treatment with MEZAVANT.

Children

Do not give MEZAVANT to children below the age of 18 years.

Other medicines and MEZAVANT:

Always tell your health care providers if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Please tell your doctor or pharmacist or other health care providers 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 medicines (for example medicines containing aspirin, ibuprofen or diclofenac).
- Azathioprine or 6-mercaptopurine (known as 'immunosuppressant' medicines), as the use of these medicines may cause blood disorders, bone marrow failure and other associated symptoms.
- Anticoagulants (used to prevent the clotting of blood.) for example warfarin. MEZAVANT can decrease the anticoagulants ability to prevent blood clotting.
- If you need to go for a urine test, tell the doctor that you are taking MEZAVANT, as it may interfere with the results.

MEZAVANT with food and drink

MEZAVANT can be taken with or without food at the same time each day.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care providers for advice before taking this medicine.

Do not use MEZAVANT when you are pregnant or breastfeeding your baby.

Safety of using MEZAVANT during pregnancy has not been established.

Some abnormalities have been reported in infants born to mothers using mesalazine (as in MEZAVANT).

Mesalazine and its N-acetyl metabolite is excreted in breast milk and can cause the breastfed baby to have excessive stools (diarrhoea). MEZAVANT is not recommended for mothers breastfeeding their babies.

Driving and using machines:

MEZAVANT is unlikely to have any effect on your ability to drive or use machines. You should not drive or operate machines until you know how MEZAVANT affects you.

It is not always possible to predict to what extent MEZAVANT may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which MEZAVANT affects you.

3. How to take use MEZAVANT

Do not share medicines prescribed for you with any other person.

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

Take your tablets at the same time each day with or without food. The tablets should be swallowed whole and must not be crushed or chewed.

The usual daily dose for adults for initiation of remission is 2,4 g to 4,8 g (two to four tablets) taken once a day.

The highest daily dose of 4,8 g (four tablets) daily is recommended for adults, if they do not respond to the lower doses of MEZAVANT.

If you are taking four tablets a day, your doctor should check how you are responding to your treatment, 8 weeks after starting treatment.

The usual adult dose for maintenance of remission is 2,4 g (two tablets) once daily.

Once your symptoms have cleared and to help prevent reoccurrence of another episode, your doctor will inform you if you need to adjust the number of tablets you are taking.

MEZAVANT should not be given to children under 18 years of age.

Safety of using MEZAVANT if you have kidney or liver problems has not been established.

(see 'Do not take MEZAVANT' and 'Take special care with MEZAVANT')

If you take more MEZAVANT than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you take too much MEZAVANT 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

It is important to take your MEZAVANT 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 MEZAVANT, ask your doctor or pharmacist.

4. Possible side effects

MEZAVANT can have side effects.

Not all side effects reported for MEZAVANT are included in this leaflet. If your general health worsens or if you experience any untoward effects while taking MEZAVANT, please consult your doctor or pharmacist or health care provider for advice.

If any of the following happens, stop taking MEZAVANT and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- skin rash or itching.
- fainting.
- fever (high body temperature).
- skin pain.
- shedding of your skin.

These are all very serious side effects. If you have them, you may have had a serious reaction to MEZAVANT. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- 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 less frequently, but means your treatment would have to be

stopped immediately.

- unexplained bruising (without injury).
- anaemia (feeling tired, weak and looking pale, especially on lips, nails and inside of eyelids).
- unusual bleeding (e.g. nose bleeds).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- hypersensitivity (allergic reactions including itching, rash, hives and swelling of the face).
- chronic digestive disease characterized by inflammation of the inner lining of the colon (known as colitis).
- headache.
- flatulence.
- nausea (feeling sick).
- vomiting.
- abdominal pain.
- diarrhoea.
- indigestion.
- abdominal swelling.
- back pain.
- joint pain.
- weakness.
- tiredness.
- abnormal liver functions tests (ALT, AST, bilirubin).

Less frequent side effects:

- sore throat.
- drowsiness.
- dizziness.

- fast or irregular heart rate.
- nervousness.
- excessive sweating.
- facial flushing.
- light-headedness.
- unsteadiness, or feeling loss of balance.
- growths on the inside of the colon or rectum.
- acne.
- hair loss.
- loss of appetite.
- less urine than what is normal for you.
- confusion.
- shortness of breath.
- low blood platelet count.
- kidney stones.

The following side effects have been reported but it is not known exactly how often they occur:

- numbness and pain in your hands and feet.
- yellowing of the skin and eyes, also called jaundice.
- muscle pain.
- blood in the urine.
- anaphylactic reaction, Steven-Johnson syndrome and DRESS syndrome (Drug Rash with Eosinophilia and Systemic Symptoms) (a severe allergic reaction).
- increased pressure inside your skull.
- lung disease and -infection.
- photosensitivity (an extreme sensitivity to ultraviolet (UV) rays from the sun and other light sources).
- kidney failure and nephrogenic diabetes insipidus (the inability to concentrate urine, which leads to the urination of large amounts of dilute urine).

- reversible low sperm count.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get 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 to SAHPRA via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of MEZAVANT.

5. How to store MEZAVANT

Store all medicines out of reach of children.

- Store at or below 25 °C
- Store in outer container until before use.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MEZAVANT contains

The active substance is mesalazine 1200 mg.

The other ingredients are carmellose sodium; carnauba wax; macrogol 6000; magnesium stearate; methacrylic acid copolymer; red ferric oxide; silica colloidal hydrated; sodium starch glycolate; stearic acid; talc; titanium dioxide; triethylcitrate.

What MEZAVANT looks like and contents of the pack

MEZAVANT are red-brown, ellipsoidal, enteric coated, prolonged-release tablets, embossed on one side with S476.

MEZAVANT tablets are packed in blisters strips of 12 tablets per blister.

Polyamide/aluminium/PVC foil with Aluminium Push-through foil blisters in packs of 60s and 120s.

The blisters strips are packaged in outer unit cartons.

Holder of Certificate of Registration

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This leaflet was last revised in

20 May 2022

Registration number

Registration number: 45/11/0463