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MEZAVANT **TAKEDA (PTY) LTD**
Each enteric coated tablet contains 1200 mg Mesalazine

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

[PRODUCT NAME] STRENGH PHARMACEUTICAL FORM:

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

Active substance: 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 healthcare provider.
- **MEZAVANT** has been prescribed only for you personally 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

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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 ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using **MEZAVANT.**
- As it may produce red-brown urine discoluoration after contact with sodium hypochlorite, bleach in the toilet water. It concerns a chemical reaction between mesalazine and bleach and is harmless.

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- 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.
- If you experience strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears contact your doctor immediately
- **MEZAVANT** may cause kidney stones. You should drink a fair amount of fluid (such as water) during treatment with **MEZAVANT**.
- Serious skin reactions including Drug reaction with eosinophilia and systemic symptoms (DRESS), Steven-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN) 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

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

Other medicines and MEZAVANT:

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Always tell your healthcare providers if you are taking any other medicine

(This includes all complementary or traditional medicines).

Please tell your doctor or pharmacist or other healthcare 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 breast-feeding

If you are pregnant or breast-feeding**,** think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare providers for advice before taking this medicine.

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Do not use **MEZAVANT** when you are pregnant or breast-feeding 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 breast-fed baby to have excessive stools (diarrhoea). **MEZAVANT** is not recommended for mothers breast-feeding their babies.

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 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.

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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

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.

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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.

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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 healthcare 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),
- enlarged lymph node,
- skin pain,
- shedding of your skin.

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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:

- acute intolerance syndrome. 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), and
- unusual bleeding (e.g., nose bleeds).
- If you experience strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears. These could be symptoms of increased pressure within your skull (idiopathic intracranial hypertension).

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),

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- headache,
- flatulence,
- nausea (feeling sick),
- vomiting,
- abdominal pain,
- diarrhoea,
- indigestion,
- abdominal swelling,
- back pain,
- joint pain,
- weakness,
- tiredness, and
- abnormal liver functions tests (ALT, AST, bilirubin).

Less frequent side effects:

- sore throat,
- drowsiness,
- dizziness,
- fast or irregular heart rate,

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- 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, and
- 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,

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- blood in the urine,
- liver damage that may present as abnormal liver tests,
- inflammation of the heart and lining around the heart,
- inflammation of the lung; difficulty in breathing or wheezing,
- skin sensitivity to sunlight along with joint pain, serious illness with blistering of the skin (possibly leading to peeling of the skin and resulting in painful, raw areas), mouth, eyes and genitals,
- any abnormal colouration of 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, and
- 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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. Additionally, suspected adverse reactions can be reported to AE.southafricassa@takeda.com or on the 24 hours contact

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number: 082 525 3040. 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.

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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.

NAME AND ADDRESS OF REGISTRATION HOLDER

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