

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

MEMANTINE UNICHEM 10 mg film-coated tablets

Memantine hydrochloride

Sugar free.

Read all of this leaflet carefully before you start taking MEMANTINE UNICHEM 10

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or health care provider.
- MEMANTINE UNICHEM 10 has been prescribed 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 MEMANTINE UNICHEM 10 is and what it is used for
2. What you need to know before you take MEMANTINE UNICHEM 10
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1. What MEMANTINE UNICHEM 10 is and what it is used for

MEMANTINE UNICHEM 10 contains the active substance memantine hydrochloride. It belongs to a group of medicines known as anti-dementia medicines. Alzheimer's disease is a form of

dementia which is a brain disorder that negatively affects a person's ability to carry out daily activities.

MEMANTINE UNICHEM 10 is used to treat the symptoms of Alzheimer's disease, such as memory loss.

2. What you need to know before you take MEMANTINE UNICHEM 10

Do not take MEMANTINE UNICHEM 10:

- If you are allergic (hypersensitive) to memantine hydrochloride or to any of the other ingredients of MEMANTINE UNICHEM 10 (listed in section 6).

MEMANTINE UNICHEM 10 should not be used in children and adolescents under the age of 18 years.

Warnings and precautions

Take special care with MEMANTINE UNICHEM 10:

Before you take MEMANTINE UNICHEM 10 tell your doctor:

- If you have a severe kidney disorder.
- If you have recently changed or intend to change your diet significantly (such as from normal diet to vegetarian diet), if you suffer from a condition called renal tubular acidosis or RTA (an excess of acid-forming substances in the blood due to a kidney disorder) or if you suffer from severe infections of the urinary tract, as your doctor may need to adjust the dose of MEMANTINE UNICHEM 10.
- If you suffer from epilepsy or have a history of seizures or fits.
- If you recently had a heart attack or have a heart disorder.
- If you have a history of high and uncontrolled blood pressure.

Other medicines and MEMANTINE UNICHEM 10

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

In particular, tell your doctor if you are taking any of the following medicines:

- Dextromethorphan (a type of cough medicine).
- Dantrolene, baclofen (used as muscle relaxants).
- Cimetidine, ranitidine (used to treat stomach ulcers or heartburn).
- Hydrochlorothiazide (water pill or any medicine used to manage high blood pressure that is in combination with hydrochlorothiazide).
- Anticholinergics (used to treat movement disorders or intestinal cramps).
- Anticonvulsants (used to prevent and relieve seizures or fits).
- Barbiturates (used to induce sleep).
- Dopaminergic agonists, such as L-dopa (used to treat Parkinson's disease) or bromocriptine (used to treat high levels of the hormone prolactin in your body).
- Neuroleptics (used in the treatment of mental disorders).
- Amantadine (used to treat Parkinson's disease).
- Ketamine (used as anaesthetic during surgery).
- Procainamide or quinidine (used to treat an abnormal heartbeat).
- Quinine (used to reduce fever and treat malaria).
- Nicotine (used as an aid to stop smoking and prevent withdrawal symptoms).
- Warfarin (used to prevent blood from clotting).

Not all medicines that may interact with MEMANTINE UNICHEM 10 are included in this leaflet.

MEMANTINE UNICHEM 10 with food and drink

MEMANTINE UNICHEM 10 may be taken with or without food.

You should inform your doctor if you have recently changed or intend to change your diet substantially (e.g. from normal diet to strict vegetarian diet), as your doctor may need to adjust the dose of MEMANTINE UNICHEM 10.

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 provider before taking MEMANTINE UNICHEM 10.

Pregnancy

Do not take MEMANTINE UNICHEM 10 if you are pregnant, suspect you are pregnant or planning to become pregnant. Contact your doctor immediately.

Breastfeeding

Do not take MEMANTINE UNICHEM 10 if you are breastfeeding your baby.

Driving and using machines

MEMANTINE UNICHEM 10 may impair your ability to drive a vehicle and use machinery.

Do not drive a vehicle, operate machinery, or perform any activities that require concentration until you know how MEMANTINE UNICHEM 10 affects you.

3. How to take MEMANTINE UNICHEM 10

- Always take MEMANTINE UNICHEM 10 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- Do not share medicines prescribed for you with any other person.
- When starting your treatment your doctor will start off with a small dose and gradually increase the dose. This allows your doctor to make sure that you have the right dose that helps your condition and avoids any unwanted symptoms.
- The usual dose is:
 - Week 1: 5 mg per day (half a tablet in the morning).
 - Week 2: 10 mg per day (half a tablet twice a day).

- Week 3: 15 mg per day (one tablet in the morning and half a tablet in the afternoon).
- Week 4: 20 mg per day (one tablet twice a day).
- The maximum dose is 20 mg per day.
- Your doctor will adjust your dose accordingly if you are elderly or suffer from moderate kidney problems.
- Make sure to take MEMANTINE UNICHEM 10 at the same time each day and try to avoid missing any doses.
- Your doctor will tell you how long your treatment with MEMANTINE UNICHEM 10 will last.
- If you have the impression that the effects of MEMANTINE UNICHEM 10 is too strong or too weak, tell your doctor or pharmacist.

If you take more MEMANTINE UNICHEM 10 than you should:

In the event of overdosage, consult your doctor or pharmacist as soon as possible. If neither is available, contact the nearest hospital or poison centre. Always take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

You may experience increased symptoms as described in section 4 below.

If you forget to take MEMANTINE UNICHEM 10:

If you have missed your dose by only a few hours, take the missed dose as soon as you remember and then continue with your normal schedule.

However, if it is almost time for your next dose, skip the missed dose and take your next dose at the usual time. Do not take a double dose to make up for a missed dose.

4. Possible side effects

MEMANTINE UNICHEM 10 can have side effects.

Not all side effects reported for MEMANTINE UNICHEM 10 are included in this leaflet. Should your general health worsen or you experience any untoward effects while taking

MEMANTINE UNICHEM 10, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking MEMANTINE UNICHEM 10 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MEMANTINE UNICHEM 10. 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:

- Shortness of breath.
- Loss of bladder control.
- Bladder infection (painful or burning urination, frequent urge to urinate).
- Seizures.
- Heart failure.
- Venous blood clotting (thrombosis/thromboembolism).
- Yellowing of your skin and eyes, also called jaundice or liver failure, hepatitis (inflammation of the liver).
- Chest pain.
- Changes in the way your heart beats (beating faster than normal).
- Stroke (weakness, loss of sensation, slurred speech, difficult movement, loss of sight).
- Unexplained bruising, pinpoint bleeds on your skin, nosebleeds or bleeding gums.
- Inhalation of foreign material (such as food, mucus or saliva) causing infection of your lungs

(chest pain, shortness of breath, wheezing, cough with sputum, blood or odour).

- Neuroleptic malignant syndrome (NMS) (fever, tight/stiff muscles, altered mental status [feeling confused, agitated or disoriented], changes in the way your heart beats, changes in your pulse rate or blood pressure and increased sweating).
- Tardive dyskinesia (uncontrolled and repetitive movements of your lips, tongue, face, arms or legs, or excessive blinking of your eyes).
- Severe, painful, blistering skin rash known as Stevens-Johnson syndrome.
- Kidney failure (weakness, tiredness, nausea, vomiting or changes in the amount of urine).

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

Tell your doctor as soon as possible if you notice any of the following:

The following side effects occur more frequently:

- Feeling confused or agitated.
- Hallucinations (seeing, hearing or sensing things that are not real).
- Difficulty sleeping (insomnia).
- Drowsiness (somnolence).
- Headache or dizziness.
- Balance disorders.
- Coughing.
- Constipation.
- Inflicted injury.
- High blood pressure (hypertension).
- Elevated liver function tests.

The following side effects occur less frequently:

- Fungal infections.
- Anorexia (severe weight loss).
- Feeling depressed or anxious.

- Changes in the way you walk.
- Involuntary muscle movements.
- Carpal tunnel syndrome (numbness, pain or tingling in your hand or arm).
- Restlessness.
- Claudication (pain or cramping in your lower legs while walking or exercising).
- Nausea (feeling sick) or vomiting (being sick).
- Diarrhoea.
- Increased muscle tone or spasms.
- Joint or back pain.
- Increased sex drive.
- Swelling of your hands, feet, arms or legs due to water retention.
- Tiredness.
- Flu-like symptoms (headache, aching muscles, tiredness).
- Generalised pain.

The following side effects can occur, but the frequencies are not known:

- High fat levels in your blood when tests are done.
- Pancreatitis (pain of your stomach are radiating to your back).
- Low blood sugar levels (confusion, dizziness, headaches, pale skin and increased heartrate).
- Intestinal obstruction caused by slow bowel movements (cramping, bloating, inability to go to the bathroom, nausea or vomiting).
- Stomach upset.
- Difficulty swallowing.
- Heartburn.
- Bone fracture.
- Inability to develop or maintain an erection.
- General discomfort.

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, pharmacist or nurse. You can also report side effects 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 MEMANTINE UNICHEM 10.

5. How to store MEMANTINE UNICHEM 10

- Store at or below 25 °C.
- Keep blister strips in outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the label or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MEMANTINE UNICHEM 10 contains

The active substance is memantine hydrochloride. Each film-coated tablet contains 10 mg memantine hydrochloride.

The other ingredients are colloidal anhydrous silica, crospovidone, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, purified talc and titanium dioxide.

What MEMANTINE UNICHEM 10 looks like and contents of the pack

Off-white, capsule shaped, biconvex, film-coated tablets, debossed with "M" and 10 on either side of the break line on one side and break line on other side. The tablet can be divided into equal halves.

Clear transparent triplex (PVC/PE/PVDC) film blister strips with aluminium foil containing 10 tablets. Six blister strips are packed in an outer carton.

Pack size: 60 tablets.

Holder of Certificate of Registration

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This leaflet was last revised in

24 January 2022

Registration number

46/5.11/0416