

MEMANTINE GENERICHEALTH TABLETS

Memantine Hydrochloride

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet contains answers to some common questions about Memantine generichealth tablets.

It does not contain all the information that is known about Memantine generichealth tablets. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risk of you using this medicine against the benefits he/she expects it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT MEMANTINE GENERICHEALTH TABLETS IS USED FOR

Memantine generichealth tablet is used to treat moderately severe to severe Alzheimer's disease (AD). AD can be described as a general decline in all areas of mental ability. Memantine generichealth tablet belongs to a group of medicines called N-methyl-D-aspartate (NMDA) receptor antagonists.

It is thought to work by protecting NMDA receptors in the brain against high levels of the chemical

glutamate, which could be the cause of brain degeneration. NMDA receptors are involved in the transmission of nerve signals within the brain, e.g. in learning and memory.

Memantine generichealth tablets should improve your thinking capacity and your ability to remember.

Your doctor, however, may prescribe it for another purpose.

Ask your doctor if you have any questions about why it has been prescribed for you.

This medicine is only available with a doctor's prescription.

Memantine generichealth tablets are not addictive.

BEFORE YOU TAKE MEMANTINE GENERICHEALTH TABLETS

When you must not take it

Do not take Memantine generichealth tablets if you are allergic to it or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, or rash, itching or hives on the skin.

Do not take Memantine generichealth tablets if you have a

seizure disorder or any history of seizures (fits or epilepsy).

Do not take Memantine generichealth tablets if you have kidney problems.

Do not take it after the expiry date printed on the pack.

If you take it after the expiry date has passed, it may not work as well. The expiry date refers to the last day of the month.

Do not take it if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if:

- 1. you have allergies to any other substances such as foods, preservatives or dyes.**
- 2. you are pregnant or intend to become pregnant.**

Memantine generichealth tablet is not recommended to be used during pregnancy. Your doctor will discuss the risks and benefits of using it if you are pregnant.

- 3. you are breast-feeding or planning to breast-feed.**

It is not known whether Memantine generichealth tablet passes into breast milk. Due to the possibility that their baby might be affected, women taking Memantine generichealth tablet should not breast-feed.

- 4. you have, or have had, the following medical conditions:**

- a history of epileptic seizures or convulsions
- kidney problems

- severe bladder infection
- liver problems
- heart or blood vessel problems
- high blood pressure

5. you smoke

Also tell your doctor if you have recently changed your diet or intend to change your diet substantially, for example if you wish to become a vegetarian.

Your doctor may need to adjust the dose.

Do not give Memantine generichealth tablet to a child or adolescent under 18 years old.

If you have not told your doctor about any of the above, tell them before you use Memantine generichealth tablet.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Memantine generichealth tablet may interfere with each other. These include:

- medicines used to treat stomach cramps or spasms, or travel sickness (anticholinergics)
- atropine, a medicine used in some eye drops
- levodopa, bromocriptine, amantadine and other medicines for the treatment of Parkinson's disease
- anticonvulsants and barbiturates, used to treat epilepsy or fits
- ketamine, an anaesthetic agent
- medicines used to treat certain mental and emotional conditions (psychoses or schizophrenia)
- dantrolene and baclofen, used to treat leg cramps or to relax muscles
- dextromethorphan, contained in cough, cold and flu medicines
- quinidine and procainamide, used to treat irregular heart beat
- nicotine, contained in patches or gums to treat smoking addiction

- cimetidine and ranitidine, used to treat stomach ulcers or reflux
- urinary alkalinisers, used to treat urinary tract infection
- quinine, a medicine used to treat malaria
- warfarin, used to prevent blood clots.

These medicines may be affected by Memantine generichealth tablet or may affect how well it works. You may need to use different amounts of your medicines, or take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Memantine generichealth tablet

HOW TO TAKE MEMANTINE GENERICHEALTH TABLETS

How much to take

The standard dose for this medicine is 20 mg per day.

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight and your response to the medicine.

Your doctor will start you on smaller doses which will be gradually increased for three weeks until the dose is reached where Memantine generichealth tablet work best for you.

Week 1 (Day 1-7)

Take half a tablet of 10 mg once a day.

Week 2 (Day 8-14)

Take 10 mg tablet once a day.

Week 3 (Day 15-21)

Take one 10 mg tablet in the morning and half a tablet in the evening.

Week 4 (Day 22-28)

Take one 20 mg tablet once a day.

The maximum daily dose is 20 mg per day.

Your doctor may have prescribed a different dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Memantine – Lupin tablet may not work as well and your condition may not improve.

How to take it

Take Memantine generichealth tablet with or without food.

Swallow the tablets whole with a full glass of water.

Do not chew them.

How long to take it

Continue taking your medicine for as long as your doctor tells you to.

Memantine generichealth tablet helps control your condition, but does not cure it. Your doctor will assess your treatment on a regular basis.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

Do not take a double dose to make up for the dose you have missed.

If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for hints.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons

Information Centre (Tel: 13 11 26 for Australia), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Memantine - Lupin tablet.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include feeling dizzy, tired or having a headache. You may feel confused and see, feel or hear things that are not there. You could also have a seizure.

WHILE YOU ARE TAKING MEMANTINE GENERICHEALTH TABLETS

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Memantine generichealth tablet.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking Memantine generichealth tablet, tell your doctor immediately.

Tell your doctor immediately if you are feeling depressed or have any suicidal thoughts.

Alzheimer's disease has been associated with depression and thoughts of suicide. All mentions of suicide or violence by a patient must be taken seriously.

If you or someone you know demonstrates suicide-related behaviour while taking Memantine generichealth tablet, contact a health care provider immediately, or even go to the nearest hospital for treatment.

Things you must not do

Do not give the tablets to anyone else, even if they have the same condition as you.

Do not take Memantine generichealth tablet to treat any other complaints unless your doctor tells you to.

Do not stop taking Memantine generichealth tablet, or lower the dosage, without checking with your doctor.

Things to be careful of

If you drive a motor vehicle or operate machinery, ask your doctor whether you should continue to do so.

Your doctor will discuss with you whether your condition allows you to drive or operate machinery safely.

Furthermore, Memantine generichealth tablet may change your reactivity which may make driving or using machinery inappropriate.

SIDE EFFECTS

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits he/she expects it will have for you.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Memantine generichealth tablets.

It helps most people with moderately severe to severe Alzheimer's disease, but it may have unwanted side effects in a few people.

Tell your doctor if you notice any of the following and they worry you:

- tiredness, sleepiness, sleeplessness, or problems sleeping
- dizziness

- diarrhoea, vomiting, or nausea
- loss of appetite
- feeling anxious
- conjunctivitis.

These are mild side effects of the medicine.

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

- swelling of hands, ankles or feet
- headache
- feeling confused
- seeing, feeling or hearing things that are not there
- having fixed, irrational ideas that are not shared by others.

These may be serious side effects of Memantine generichealth tablet.

You may need urgent medical attention.

If you are an epileptic, Memantine generichealth tablet could increase the chance of a fit occurring.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- serious allergic reaction (symptoms of an allergic reaction may include swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, or hives).

This is a very serious side effect.

You may need urgent medical attention or hospitalisation.

This side effect is very rare.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some people.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

AFTER TAKING MEMANTINE GENERICHEALTH TABLETS

Storage

Keep Memantine generichealth tablet in the blister pack until it is time to take them.

If you take the tablets out of the box or the blister pack they may not keep well.

Keep the medicine in a cool dry place where the temperature stays below 25 degrees C.

Do not store Memantine generichealth tablet or any other medicine in the bathroom, near a sink, or on a window-sill.

Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking the tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

PRODUCT DESCRIPTION

What it looks like

- Memantine generichealth tablet 5 mg – White to off white colored, capsule shaped, biconvex, film coated tablets, debossed with ‘5’ on one side and plain on other side.
- Memantine generichealth tablet 10 mg – White to off white colored, oval shaped, film-coated tablets debossed with

‘10’ on one side and ‘scoreline’ on the other side.

- Memantine generichealth tablet 15 mg – Mustard coloured, oval shaped, film-coated tablets, debossed with ‘15’ on one side and plain on other side.
- Memantine generichealth tablet 20 mg – Brownish pink coloured, oval shaped, film-coated tablets debossed with ‘20’ on one side and ‘scoreline’ on the other side.

A box contains 56 tablets.

Ingredients

Active ingredient(s):

- Memantine -Lupin 5 mg tablets :
5 mg memantine hydrochloride (equivalent to 4.15 mg memantine)
- Memantine -Lupin 10 mg tablets :
10 mg memantine hydrochloride (equivalent to 8.31 mg memantine)
- Memantine -Lupin 15 mg tablets :
15 mg memantine hydrochloride (equivalent to 12.46 mg memantine)
- Memantine -Lupin 20 mg tablets :
20 mg memantine hydrochloride (equivalent to 16.62 mg memantine)

Inactive ingredients (for 5, 10, 15 and 20 mg tablets):

- Silicified cellulose - microcrystalline
- Croscarmellose sodium
- Talc - purified
- Magnesium stearate

Coating agents:

For 5 mg and 10 mg: Opadry 03B28796 White (contains Hypromellose, Titanium dioxide and Macrogol 400)

For 15 mg: Opadry 03B82943 Yellow (contains Hypromellose, Titanium dioxide, Macrogol 400 and Iron oxide yellow)

For 20 mg: Opadry 03B84713 Pink (contains Hypromellose, Titanium dioxide, Macrogol 400 and Iron oxide red)

Memantine -Lupin tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Manufacturer/Sponsor

Memantine -Lupin tablets are made by Lupin Limited, India.

Distributed in Australia by:

Lupin Australia Pty Ltd
Suite 6, Skipping girl place, 651
Victoria street,
Abbotsford, Victoria 3067-
Australia.

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Australian Registration Numbers:

Memantine Generichealth Tablets
5 mg AUST R 168424
10 mg AUST R 168425
15 mg AUST R 168426
20 mg AUST R 168427