Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using APO-Memantine?

APO-Memantine contains the active ingredient memantine (as memantine hydrochloride). APO-Memantine 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.

For more information, see Section <u>1. Why am I using APO-Memantine?</u> in the full CMI.

2. What should I know before I use APO-Memantine?

Do not use if you have ever had an allergic reaction to APO-Memantine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use APO-Memantine? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-Memantine and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use APO-Memantine?

- APO-Memantine should be taken once a day and should be taken at the same time every day.
- Follow all directions given to you by your doctor and pharmacist carefully.

More instructions can be found in Section <u>4. How do I use APO-Memantine?</u> in the full CMI.

5. What should I know while using APO-Memantine?

| Things you should do | Remind any doctor, dentist or pharmacist you visit that you are using APO-Memantine. Tell your doctor if you are about to be started on any new medicine. Tell your doctor if you are about to have any blood tests. Tell your doctor if you are going to have surgery or an anaesthetic or are going into hospital. | |
|--------------------------------|---|--|
| Things you should not do | Do not stop using this medicine suddenly or lower the dosage, without checking with your doctor. Do not take your medicine to treat any other complaints unless your doctor or pharmacist tells you to. Do not give this medicine to anyone else, even if their symptoms seem similar to yours. | |
| Driving or using machines | Be careful when driving or operating machinery until you know how this medicine affects you. Your doctor will discuss with you whether your condition allows you to drive or operate machinery safely. | |
| Looking after your medicine | Keep your medicine in a cool dry place where the temperature will stay below 25°C. Keep your medicine in its original packaging until it is time to take it. | |

For more information, see Section 5. What should I know while using APO-Memantine? in the full CMI.

6. Are there any side effects?

Tell your doctor as soon as possible if you do not feel well while you are taking APO-Memantine or if you have any concerns. Possible side effects include tiredness, sleeplessness, problems sleeping, dizziness, diarrhoea, vomiting, nausea, loss of appetite, feeling anxious, conjunctivitis or inflammation of the liver and/or changes in the liver function tests.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side effects?</u> in the full CMI.

APO-MEMANTINE

Active ingredient: memantine hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-Memantine. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using APO-Memantine.

Where to find information in this leaflet:

- 1. Why am I using APO-Memantine?
- 2. What should I know before I use APO-Memantine?
- 3. What if I am taking other medicines?
- 4. How do I use APO-Memantine?
- 5. What should I know while using APO-Memantine?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using APO-Memantine?

APO-Memantine contains the active ingredient memantine (as memantine hydrochloride). Memantine belongs to a group of medicines called N-methyl-Daspartate (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.

This medicine should improve your thinking capacity and your ability to remember.

There is no evidence that this medicine is addictive.

APO-Memantine 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.

Ask your doctor if you have any questions about why it has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

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

2. What should I know before I use APO-Memantine?

Warnings

Do not use APO-Memantine if:

- you are allergic to memantine, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

- You have seizure disorder or a history of seizures (fits or epilepsy).
- The expiry date printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.

Check with your doctor if you:

- have any other medical conditions.
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects?</u>

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not take APO-Memantine if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

3. What if I am taking other medicines?

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

Some medicines may interfere with APO-Memantine and affect how it works. 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 or if you smoke
- 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

• Anticoagulant medications such as warfarin, used to prevent blood clots.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with Memantine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APO-Memantine.

4. How do I use APO-Memantine?

How much to take

- Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.
- 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 works best for you.
- Week 1 (5 mg per day)
 Take half a 10mg tablet (white):
- Week 2 (10mg per day): Take one 10mg tablet (white).
- Week 3 (15 mg per day): Take one and a half 10mg tablet (white).
- From Week 4 onwards (20mg per day): Take two 10mg tablets (white) or one 20mg tablet (pale red).

Do not stop taking your medicine or change your dosage without first checking with your doctor.

When to take APO-Memantine

- Take APO-Memantine at the same time each day will have the best effect. It will also help you remember when to take it.
- Continue taking your medicine for as long as your doctor tells you.

How to take APO-Memantine

- Swallow the tablets with a full glass of water. Do not chew them.
- It does not matter if you take it before, with or after food.

If you forget to use APO-Memantine

APO-Memantine should be used regularly at the same time each day.

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

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

This may increase the chances of you experiencing side effects.

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

If you use too much APO-Memantine

If you think that you have used too much APO-Memantine, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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.

5. What should I know while using APO-Memantine?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using APO-Memantine.

Tell your doctor that you are taking this medicine if:

- You are about to be started on any new medicine
- You are pregnant or are planning to become pregnant
- You are breastfeeding or are planning to breastfeed
- You are about to have any blood tests
- You are going to have surgery or anaesthetic or going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for check-up.

Things you should not do

- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not take your medicine to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not stop using this medicine suddenly, or lower the dosage, without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how APO-Memantine affects you.

Your doctor will discuss with you whether your condition allows you to drive or operate machinery safely. Furthermore, memantine may change your reactivity which may make driving or using machinery inappropriate. 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, contact a health care provider immediately, or go to the nearest hospital for treatment.

Looking after your medicine

- Keep your medicine in a cool dry place where the temperature will stay below 25°C.
- Keep your medicine in its original packaging until it is time to take them.
 If you take the tablets out of their original packaging they may not keep well.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

| Less serious side effects | What to do |
|--|---|
| tiredness, sleeplessness or problems sleeping dizziness diarrhoea, vomiting, or nausea loss of appetite feeling anxious conjunctivitis inflammation of the liver and/or changes in liver function tests. | Speak to your doctor if you have any of these less serious side effects and they worry you. |

Serious side effects

| Serious side effects | What to do |
|---|--|
| swelling of hands, ankles or feet headache feeling confused seeing, feeling or hearing things that are not there | Call your doctor straight away, or go straight to the Emergency Department at |

| having fixed, irrational ideas that are not shared by others depression or suicidal thoughts. | your nearest hospital if you notice any of |
|---|--|
| Allergic reactions Symptoms of an allergic reaction may include some or all of the following: cough, shortness of breath, wheezing or difficulty breathing swelling of the face, lips, tongue, throat or other parts of the body rash, itching or hives on the skin fainting hay fever-like symptoms. | these serious side effects. |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/reporting-problems</u>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What APO-Memantine contains

| Active ingredient | memantine hydrochloride |
|---|--|
| (main ingredient) | |
| Other ingredients (inactive ingredients) | 10mg contains: Lactose monohydrate Microcrystalline cellulose Croscarmellose sodium Magnesium stearate Hypromellose Hyprolose Macrogol 8000 Titanium dioxide |
| | 20mg contains: Microcrystalline cellulose Croscarmellose sodium Methylcellulose Magnesium stearate Hypromellose Hyprolose Macrogol 8000 Titanium dioxide Iron oxide red |

| | Iron oxide yellow. | |
|---------------------|--------------------------------|--|
| Potential allergens | 10mg Tablets contain sugars as | |
| | lactose | |

Do not take this medicine if you are allergic to any of these ingredients.

What APO-Memantine looks like

APO-Memantine 10mg tablets is white, peanut shaped, biconvex film coated tablet. Engraved "APO" bisect "APO" on one side, "MEM" bisect "10" on the other side.

Aust R 159582 - Blister pack Aust R 159576 - Bottle pack

APO-Memantine 20mg tablets is pale red, oval, biconvex, coated tablet. Engraved "MEM 20" on one side, "APO" on the other side.

Aust R 207782 - Blister pack

Who distributes APO-Memantine

Arrotex Pharmaceuticals Pty Ltd 15-17 Chapel Street Cremorne VIC 3121 www.arrotex.com.au

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