### **Consumer Medicine Information**

#### What is in this leaflet

This leaflet answers some common questions about MEMANXA.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking MEMANXA against the benefits they expect it will have for you.

Talk to your doctor or pharmacist if you have any concerns about taking this medicine.

**Keep this leaflet with your medicine.** You may need to read it again.

## What MEMANXA is used for

MEMANXA is used to treat the symptoms of moderately severe to severe Alzheimer's Disease (AD). AD can be described as a general decline in all areas of mental ability.

MEMANXA belongs to a group of medicines called N-methyl-D-aspartate (NMDA) receptor antagonists. It is thought to work by protecting NDMA 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, for example in learning and memory.

MEMANXA should improve your thinking capacity and your ability to remember.

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

# Before you take it

When you must not take it

Do not take MEMANXA if you are allergic to medicines containing memantine or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

# Do not take MEMANXA if you have:

- · severe kidney problems
- a seizure disorder or any history of seizures (fits or epilepsy).

Do not take this medicine if the expiry date (Exp.) printed on the pack has passed.

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

**Do not give your medicine to children.** The safety and effectiveness in children has not been established.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

MEMANXA is not recommended for use during pregnancy. Your doctor will discuss the risks and benefits of taking this medicine while pregnant.

# Tell your doctor if you are breastfeeding or wish to breastfeed.

It is not known whether MEMANXA passes into breast milk. It is not recommended for women taking this medicine to breastfeed as it is possible their baby may be affected.

# Tell your doctor if you have, or have had, any medical conditions, especially the following:

- a history of epileptic seizures or convulsions
- · kidney problems
- · severe bladder infection
- liver problems
- · problems with the heart or blood vessels
- high blood pressure.

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.

Tell your doctor if you smoke or are using nicotine patches or replacement therapy. If you have not told your doctor about any of the above, tell them before you start taking MEMANXA.

Taking other medicines

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

Some medicines may be affected by MEMANXA, or may affect how well it works. These include:

- anticholinergic medicines, used for stomach cramps or spasms, or travel sickness
- medicines for stomach ulcers or reflux such as cimetidine, ranitidine
- atropine, a medicine used in some eye drops
- medicines for Parkinson's disease such as levodopa, bromocriptine, amantadine
- anticonvulsants and barbiturates, used to treat epilepsy or fits
- ketamine, an anaesthetic agent
- medicines for certain mental and emotional conditions including psychoses or schizophrenia
- dantrolene and baclofen, used to treat leg cramps or to relax muscles
- dextromethorphan, contained in cough, cold and flu medicines
- medicines for irregular heart beat such as quinidine, procainamide
- nicotine, contained in patches or gums to treat smoking addiction
- urinary alkalinisers, medicines for urinary tract infection
- quinine, a medicine used to treat malaria
- warfarin, a medicine used to treat blood clots.

Your doctor can tell you what to do if you are taking any of these medicines.

#### If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking MEMANXA.

# How to take it

#### How much to take

The usual dose is 20 mg per day. Your doctor will tell you how many tablets you need to take each day and when to take them. This depends on your condition, your weight and your response to the medicine.

When you start taking MEMANXA, your doctor will start you at a low dose and gradually increase it until the dose that works for your condition is reached.

The usual starting dose is 5 mg (half a tablet) once a day for the first week.

In the second week this is increased to 10 mg (one tablet) once a day.

In the third week the dose is increased to 15 mg (one and a half tablets) once a day.

From the fourth week on, the recommended dose is 20 mg (two tablets) once a day.

Follow all directions given to you by your doctor and pharmacist carefully.

How to take it

Swallow the tablets with a glass of water. MEMANXA can be taken with or without food.

If you forget to take it

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

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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

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.

How long to take it for

Keep taking MEMANXA for as long as your doctor recommends.

This medicine helps to control your condition, but it does not sure it.

Your doctor should assess your treatment on a regular basis.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much MEMANXA. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much MEMANXA, you may feel dizziness, tired or have a headache. You may also feel confused and see, hear or feel things that are not there.

# While you are taking it

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking MEMANXA.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking MEMANXA.

If you become pregnant while taking this medicine, tell your doctor immediately. If you are a woman of childbearing age, you should avoid becoming pregnant while taking it.

Visit your doctor regularly so they can check on your progress.

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

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

If you or some-one you know demonstrates suicide-related behaviour while taking this medicine, contact a health care provider immediately, or even got to the nearest hospital for treatment.

Things you must not do

Do not use this medicine to treat any other conditions unless your doctor tells you to.

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

Do not stop taking it or lower the dosage without checking with your doctor.

Things to be careful of

If you drive a motor vehicle or operate machinery you should ask your doctor whether it is safe to do so.

Your doctor will discuss whether your condition allows you to drive and use machines safely.

MEMANXA may also change your reactivity, thus making you less able to drive and use machines.

# Side effects

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

Like all other medicines, it may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- · dizziness, feeling off balance
- · feeling confused
- tiredness, sleepiness
- sleeplessness or trouble sleeping
- · feeling anxious
- diarrhoea, vomiting or nausea
- loss of appetite
- conjunctivitis.

These side effects are usually mild.

MEMANXA may cause inflammation of the liver and/or changes in liver function tests.

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

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

These may be serious side effects of MEMANXA. You may need urgent medical attention.

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 skin rash, itching or hives, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath).

This is a very serious side effect.

You may need urgent medical attention or hospitalisation. Allergic reactions are very rare

If you are an epileptic, this medicine could increase the chance of a fit occurring.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

# After using it

#### Storage

Keep MEMANXA 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.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store this, or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

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

# Product description

What it looks like

MEMANXA is an oval white scored tablet. Each pack contains 56 tablets.

Ingredients

The active ingredient in MEMANXA is memantine hydrochloride. Each tablet contains 10 mg of memantine hydrochloride.

The tablets also contain:

- microcrystalline cellulose
- lactose monohydrate
- · magnesium stearate
- hypromellose
- macrogol 6000
- titanium dioxide.

The tablets contains sugars as lactose. The tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

# Supplier

Arrotex Pharmaceuticals Pty Ltd 15-17 Chapel Street Cremorne VIC 3121 Australian registration numbers: MEMANXA - AUST R 152754

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