PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: Schedule 4.

EMORIX 10 mg film-coated tablets.

Memantine hydrochloride

Sugar free.

Read all of this leaflet carefully before you start taking EMORIX.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider
- EMORIX 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 EMORIX is and what it is used for
2. What you need to know before you take EMORIX
3. How to take EMORIX
4. Possible side effects
5. How to store EMORIX
6. Contents of the pack and other information

1. What EMORIX is and what it is used for

EMORIX contains memantine hydrochloride. It belongs to a group of medicines called NMDA receptor antagonists which are anti-dementia medicines. Memory loss in Alzheimer's disease

is due to a disturbance of message signals in the brain. The brain contains N-methyl-D-aspartate (NMDA)-receptors that are involved in transmitting nerve signals important in learning and memory. EMORIX acts on these NMDA-receptors improving the transmission of nerve signals and the memory.

EMORIX is used to treat moderately severe to severe Alzheimer's disease.

2. What you need to know before you take EMORIX Do NOT take EMORIX:

- If you are hypersensitive (allergic) to memantine or any of the other ingredients of EMORIX.
- if you are younger than 18 years.

Warnings and precautions:

Take special care with EMORIX:

You should not take medicines such as amantadine (for the treatment of Parkinson's disease), ketamine (a substance generally used as an anaesthetic), dextromethorphan (generally used to treat cough) if you are already taking EMORIX.

Tell your doctor

- If your kidneys do not work well.
- If you suffer from epilepsy (fits).
- if you change your diet from meat to vegetarian, or frequently take antacids.
- if you have recently experienced a myocardial infarction (heart attack), or if you are suffering from congestive heart failure or from an uncontrolled hypertension (high blood pressure).

Other medicines and EMORIX

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, EMORIX may change the effects of the following medicines and their dose may need to be adjusted by your doctor:

- The use of Amantadine (used to treat respiratory infections), ketamine and dextromethorphan should be avoided as central nervous system (the part of the nervous system comprising the brain and spinal cord) related side-effects may be more frequent or more pronounced.
- The effects of dopaminergic agonists (medicines such as L-dopa and bromocriptine) and anticholinergics (these are medicines generally used to treat movement disorders or intestinal cramps) may be enhanced by simultaneous treatment with EMORIX.
- The effects of barbiturates (medicines generally used to induce sleep) and neuroleptics (medicines used in the treatment of mental disorders) may be reduced by simultaneous treatment with EMORIX.
- Simultaneous treatment with EMORIX and antispasmodic medicines (muscle relaxants such as dantrolene or baclofen) can change their effects and a dose adjustment may be necessary.
- Medicines such as cimetidine, ranitidine (medicines for treating stomach ulcers), quinidine, procainamide (medicines to slow an overactive heart), quinine (malaria medicine), and nicotine medicine to help you stop smoking) may interact with EMORIX and may lead to a

risk of increased levels in the blood.

- Hydrochlorothiazide (water tablets) used together with EMORIX may decrease the diuretic effect.
- Close monitoring of prothrombin time (a test used to help diagnose bleeding or clotting disorders) or international normalized ratio (INR) (a calculation that measures the time for the blood to clot) is advisable with the simultaneous treatment of oral anticoagulants (such as warfarin, used to thin the blood) and EMORIX.

EMORIX with food and drink:

There are no interactions with food or drink when taking Emorix. (See **"HOW TO TAKE EMORIX"**)

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 for advice before taking this medicine.

Pregnancy:

- Do not use EMORIX if you are pregnant.

Breastfeeding:

- Do not use EMORIX if you are breastfeeding your baby.

Fertility:

- No effects of EMORIX on male and female fertility were observed.

Driving or using machinery:

Alzheimer's disease usually affects the ability to drive or operate machinery. Emorix may cause a change in the ability to react, therefore take special care when driving or operating machinery.

EMORIX may cause dizziness, sleepiness or drowsiness, therefore do not drive, operate complex machinery or engage in other potentially dangerous activities until it is known whether EMORIX affects your ability to perform these activities.

3. HOW TO TAKE EMORIX:

Do not share medicines prescribed for you with any other person.

Always take EMORIX exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

You will start treatment with EMORIX under the supervision of a doctor experienced in the diagnosis and treatment of Alzheimer's disease You should have a caregiver to help you take the correct dose each day.

The recommended adult starting dose of EMORIX is half a tablet twice daily. Your doctor will increase your dose every week until a maintenance dose of one tablet twice a day is achieved.

EMORIX can taken with or without food.

If you have kidney problems, your doctor will reduce the maintenance dose.

Your doctor will tell you how long your treatment with EMORIX will last. Do not stop treatment early. If you have the impression that the effect of EMORIX is too strong or too weak, tell your

doctor or pharmacist.

If you take more EMORIX than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Signs and symptoms of overdose include tiredness, weakness, diarrhoea, confusion, drowsiness, sleepiness or drowsiness, dizziness, agitation, aggression, abnormal gait, vomiting, double vision, agitation, restlessness, psychosis (a mental disorder characterised by a disconnection from reality), visual hallucinations (seeing things that do not exist outside your mind), fits, stupor and unconsciousness.

If you forget to take EMORIX:

Always take EMORIX as prescribed (see **"HOW TO TAKE EMORIX"**). If you have missed a dose, wait and take the next dose at the usual time. Do not take a double dose of EMORIX to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS:

EMORIX can have side effects.

Not all side-effects reported for EMORIX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking EMORIX, please consult your health care provider for advice.

If any of the following happens, stop taking EMORIX 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
- Rash or itching
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to EMORIX. 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:

- Anxiety, balance disorder, dizziness, fall
- Coughing, difficulty breathing
- Confusion, hallucinations
- Walking abnormalities, fits
- Blood clots.

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:

- Trouble falling or staying asleep, sleepiness or drowsiness;
- High blood pressure
- Constipation, diarrhoea
- Inflamed liver
- Leakage of urine
- Inflicted injury, headache.

Less frequent side effects:

- Fungal infections; inflammation of the bladder
- Heart failure
- Vomiting
- Hypertonia (a condition in which there is too much muscle tone so that arms or legs, for example, are stiff and difficult to move)
- Increased libido
- Liver infection
- Tiredness.

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 or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 and to Unicorn Pharmaceuticals (Pty) Ltd to vigilance@unicornpharma.co.za.

By reporting side effects, you can help provide more information on the safety of EMORIX.

5. How to store EMORIX

Store at or below 25 °C.

Keep blisters in carton until required for use.

Return all unused **EMORIX** to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF THE REACH OF CHILDREN.

6. Contents of the pack and other information What EMORIX contains

Each EMORIX film-coated tablet contains memantine hydrochloride. The other ingredients are:

Microcrystaline cellulose, povidone K-25, croscarmellose sodium and magnesium stearate.

The coating of the tablet contains:

Hydroxipropylcellulose and talc.

What EMORIX looks like and contents of the pack

Oblong biconvex white film-coated tablets, bearing a break mark.

EMORIX is packaged in transparent blisters, sealed against aluminum hard foil. The blisters are packed in an outercardboard carton.

EMORIX film-coated tablets are available in blister packs of: 14, 28, 56, 98 and 112 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Unicorn Pharmaceuticals (Pty) Ltd

Corner of Searle and Pontac Streets

Cape Town 8001

Registration number(s)

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