Patient information leaflet for Donepezil Unicorn 5 and 10

SCHEDULING STATUS

S5

Donepezil Unicorn 5 film coated tablet

Donepezil Unicorn 10 film coated tablet

Donepezil hydrochloride.

Contains lactose monohydrate

Read all of this leaflet carefully before you start taking Donepezil Unicorn.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. (See **section 4**)
- **Donepezil Unicorn** 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 Donepezil Unicorn is and what it is used for
2. What you need to know before you take Donepezil Unicorn
3. How to take Donepezil Unicorn
4. Possible side effects
5. How to store Donepezil Unicorn
6. Contents of the pack and other information.

1. What Donepezil Unicorn is and what it is used for

DONEPEZIL UNICORN (donepezil hydrochloride) belongs to a class of medicines known as cholinomimetics.

DONEPEZIL UNICORN is indicated for the treatment of symptoms of mild to moderate absence of mind in patients with Alzheimer's disease.

2. What you need to know before you take Donepezil Unicorn

Do not take Donepezil Unicorn:

- If you are hypersensitive (allergic) to donepezil hydrochloride or any of the other ingredients of DONEPEZIL UNICORN (see **section 6**).
- If you are recovering from a bladder or stomach operation.
- If you are pregnant or breastfeeding (see **Pregnancy and breastfeeding**).
- Children should not take Donepezil Unicorn.

Warnings and precautions

Take special care with Donepezil Unicorn:

- If you have a heart condition or a history of heart disease.
- If you have a stomach ulcer or a history of gastric ulcers.
- If you have bladder problems (difficulty urinating).
- If you have a history of seizures or epilepsy.
- If you have a lung disorder or a disease such as asthma.

Your specialist or doctor will diagnose your condition and determine the correct treatment.

Regular visits to your doctor may be necessary to determine if the treatment is still effective. The dosage may be adjusted, or the medication may be stopped altogether. Inform your doctor or anaesthetist that you are using DONEPEZIL UNICORN before going for surgery.

Children and adolescents

The safety and efficacy of Donepezil Unicorn in children is not known, therefore it is not recommended for use in children.

Other medicines and DONEPEZIL UNICORN

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

The following medicines may interact with DONEPEZIL UNICORN and cause undesirable side effects:

- Dexamethasone (used in conditions with inflammation).
- Nonsteroidal anti-inflammatory medicines (painkillers).
- Medicines used for cramps or spasm of the stomach or bladder.
- Medicines used in the treatment of seizures (carbamazepine, phenytoin and phenobarbital).
- Medicines used in the treatment of tuberculosis (TB) (e.g. rifampicin).
- Medicines used in treatment of fungal infections (such as ketoconazole).
- Medicines used in the treatment of irregular heartbeats (such as quinidine, amiodarone, sotalol)
- Medicines used in the treatment of depression (such as citalopram, escitalopram, amitriptyline)
- Medicines used in the treatment of psychosis (a collection of symptoms that affect the mind) (such as phenothiazine derivatives, sertindole, pimozide, ziprasidone)
- Antibiotics used to treat certain bacterial infections (clarithromycin, erythromycin, levofloxacin, moxifloxacin

Donepezil Unicorn with food and drink:

DONEPEZIL UNICORN can be taken with or without food.

Pregnancy and breastfeeding:

Do not use DONEPEZIL UNICORN if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking Donepezil Unicorn**.**

Driving and using machinery:

Donepezil Unicorn may make you drowsy or impair your ability to drive a vehicle and use machinery. Take care until you know how DONEPEZIL UNICORN affects you.

Donepezil Unicorn contains lactose monohydrate

DONEPEZIL UNICORN contains lactose monohydrate, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking DONEPEZIL UNICORN.

3. How to take Donepezil Unicorn

Always take DONEPEZIL UNICORN exactly as your doctor has instructed you.
You should check with your doctor or pharmacist if you are unsure.
The usual dose is one DONEPEZIL UNICORN tablet every day in the evening.
Your doctor will tell you how long your treatment with DONEPEZIL UNICORN will last.

If you have the impression that the effect of DONEPEZIL UNICORN is too strong or too weak, tell your doctor or pharmacist.

If you take more Donepezil Unicorn than you should:

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

If you forget to take Donepezil Unicorn:

If you miss a dose of DONEPEZIL UNICORN, take it as soon as you remember. Do not take DONEPEZIL UNICORN if it has been more than 12 hours since you missed your last dose.
Wait and take the next dose at your regular time.
Do not take a double dose of DONEPEZIL UNICORN to make up for a missed dose.

If you stop taking Donepezil Unicorn

Do not stop taking DONEPEZIL UNICORN unless your doctor tells you to.
If you have any further questions on the use of DONEPEZIL UNICORN, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

DONEPEZIL UNICORN can have side effects.
Not all side effects reported for DONEPEZIL UNICORN are included in this leaflet.
Should your general health worsen or if you experience any untoward effects while taking DONEPEZIL UNICORN, please consult your doctor, pharmacist or other healthcare professional for advice.
If any of the following happens, stop taking DONEPEZIL UNICORN and tell your doctor immediately or go to the casualty department at your nearest hospital:

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

- Neuroleptic malignant syndrome (a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions).

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

Less frequent:

- Chest pain, slow or irregular heartbeat.
- Signs of recurrent infection such as fever and sore throat.
- Difficulty breathing.
- The need to wake up at night and pass urine (nocturia).
- Frequent urination or inability to control urination.
- Bladder infections.

Frequency unknown:

- Changes in the heart activity which can be seen on an electro-cardiogram (ECG) called 'prolonged QT interval'
- Yellowing of the skin and eyes, also called jaundice.
- Inflammation of the pancreas.

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:

Frequent:

- Loss of appetite.
- Sleep disorders, tiredness, agitation.

- Diarrhoea, nausea (feeling sick), vomiting (being sick), heartburn.
- Muscle cramps.

Less frequent:

- Bruising.
- Dehydration (loss of body fluids).
- Mental depression.
- Dizziness (vertigo), abnormal dreams, restlessness, nervousness.
- Headache, drowsiness, fainting.
- Tingling or numbness of the hands and feet, tremors (shaking).
- Unsteadiness when walking.
- Inability (or impaired ability) to understand or produce speech, as a result of brain damage (aphasia).
- Mood disorders, aggression, delusions, irritability.
- Blurred vision, eye irritation.
- Hot flushes, changes in blood pressure.
- Stomach ulcers, constipation, weight loss, bloating, abdominal pain, blood in the stools.
- Itchy rash, unusual sweating.
- Painful joints, bone fractures.
- Increased sex drive.
- Toothache.

Frequency unknown:

- A condition in which there is a decreased number of red blood cells in the body.
- Low sodium levels in the blood.
- Confusion, seeing things that are not there, fits.
- Inflammation of the gall bladder.

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 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 or directly to Unicorn Pharmaceuticals (Pty) Ltd. at vigilance@unicornpharma.co.za. By reporting side effects, you can help provide more information on the safety of DONEPEZIL UNICORN.

6. How to store Donepezil Unicorn

- Store in a dry place at or below 25 °C.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the carton.
- Do not remove a tablet from the blister strip until you are ready to use the dose.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. Contents of the pack and other information

What Donepezil Unicorn contains

The active substance in DONEPEZIL UNICORN is donepezil hydrochloride.

Each DONEPEZIL UNICORN 5 film coated tablet contains 5 mg donepezil hydrochloride.

Each DONEPEZIL UNICORN 10 film coated tablet contains 10 mg donepezil hydrochloride.

The other ingredients are croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, Opadry (macrogol, polyvinyl alcohol, talc, titanium dioxide).

DONEPEZIL UNICORN 10 also contains yellow iron oxide (colourant).

8. What Donepezil Unicorn looks like and contents of the pack

DONEPEZIL UNICORN 5: White, round, biconvex, film coated tablet with D5 debossed on one side and plain on the other side.

DONEPEZIL UNICORN 10: Yellow, round, biconvex, film coated tablet with D10 debossed on one side and plain on the other side.

DONEPEZIL UNICORN: is presented in a transparent PVC/PVDC/silver aluminium foil blister strips of 10 tablets each.

30 tablets packed into an outer carton.

Holder of Certificate of Registration

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