PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

NEPIZEL 5 mg film-coated tablet

NEPIZEL 10 mg film-coated tablet

Donepezil hydrochloride.

Contains sugar.

NEPIZEL 5: Each film-coated tablet contains 98 mg lactose monohydrate.

NEPIZEL 10: Each film-coated tablet contains 192 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking NEPIZEL

- 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.
- NEPIZEL 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 NEPIZEL is and what it is used for

NEPIZEL contains an active ingredient called donepezil hydrochloride, which belongs to a group of medicines called cholinomimetics.

NEPIZEL is used to treat the symptoms of mild to moderate absence of mind in patients with Alzheimer's disease.

2. What you need to know before you take NEPIZEL

Do not take NEPIZEL:

- If you are hypersensitive (allergic) to donepezil hydrochloride, piperidine derivatives or any of the other ingredients of NEPIZEL (listed in section 6).
- If you are recovering from a bladder or stomach operation.
- If you are pregnant or breastfeeding (see Pregnancy and breastfeeding).
- If you are a child or adolescent below 18 years of age.

Warnings and precautions

Take special care with NEPIZEL if you have or previously had:

- A heart condition or heart disease.
- A stomach ulcer.
- Bladder problems (difficulty urinating).
- Seizures (fits) or epilepsy.
- 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 all together. Inform your doctor or anaesthetist, that you are using NEPIZEL before going for surgery.

Children and adolescents

The safety and efficacy of NEPIZEL in children and adolescents below the age of 18 is not known, therefore it is not recommended for use in children.

Other medicines and NEPIZEL

Always tell your health care provider if you are taking any other medicine (this includes all complementary or traditional medicines).

The following medicines may weaken or strengthen the effects of NEPIZEL:

- Medicines used to treat fungal infections (such as ketoconazole and itraconazole).
- Antibiotics used to treat certain bacterial infections (such as erythromycin, clarithromycin, levofloxacin and moxifloxacin).
- Dexamethasone (used in conditions inflammatory conditions).
- Nonsteroidal anti-inflammatory drugs (NSAIDs) (used to treat pain, fever and inflammation).
- Medicines used for cramps or spasm of the stomach or bladder.
- Medicines used in the treatment of seizures (fits) (carbamazepine, phenytoin and phenobarbital).
- Medicines used in the treatment of tuberculosis (TB) (e.g. rifampicin).
- Medicines for heart rhythm disorders (e.g. quinidine, beta-blockers, amiodarone, sotalol).
- Antidepressants, such as citalopram, escitalopram, amitriptyline and fluoxetine.
- Medicines used to treat psychosis (such as sertindole, pimozide and ziprasidone).

NEPIZEL with food and drink

NEPIZEL can be taken with or without food.

NEPIZEL should not be taken with alcohol as alcohol may decrease the effect of NEPIZEL.

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 NEPIZEL.

The safety of NEPIZEL in pregnancy and breastfeeding has not been established. You should therefore not take NEPIZEL if you are pregnant or breastfeeding your baby.

Driving and using machines

Alzheimer's disease may affect your ability to drive and use machines. Furthermore, NEPIZEL may cause drowsiness, dizziness and muscle cramps which may also impair your ability to drive a vehicle and use machinery. Do not drive a vehicle or operate machines until you know how NEPIZEL affects you.

NEPIZEL contains lactose monohydrate

NEPIZEL 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 NEPIZEL.

3. How to take NEPIZEL

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

Always take NEPIZEL exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is one NEPIZEL tablet every day in the evening.

NEPIZEL can be taken with or without food.

Your doctor will tell you how long your treatment with NEPIZEL will last.

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

If you take more NEPIZEL 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 NEPIZEL

If you miss a dose of NEPIZEL, take it as soon as you remember. Do not take NEPIZEL 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 NEPIZEL to make up for forgotten individual doses.

If you stop taking NEPIZEL

Do not stop taking NEPIZEL unless your doctor tells you to.

If you have any further questions on the use of NEPIZEL, ask your doctor or pharmacist.

4. Possible side effects

NEPIZEL can have side effects.

Not all side effects reported for NEPIZEL are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking NEPIZEL, please consult your health care provider for advice.

If any of the following happens, stop taking NEPIZEL 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 reaction to NEPIZEL. 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:

- Chest pain, slow or irregular heartbeat.
- Changes in heart activity which can be seen on an electro-cardiogram (ECG) called 'prolonged QT interval'.
- Difficulty breathing.
- Bladder infections.
- Liver problems including yellowing of the skin and eyes, also called jaundice or hepatitis.
- Pancreatitis (nausea, vomiting, fever, pain in your stomach area radiating to your back).

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:

- Loss of appetite, weight loss.
- Sleep disorders, abnormal dreams and nightmares, tiredness, agitation.
- Diarrhoea, nausea (feeling sick), vomiting (being sick), heartburn, abdominal disturbance.
- Muscle cramps.
- Frequent urination or inability to control urination.
- Depression, aggressive behaviour, delusions, seeing things that are not there.
- Headache, dizziness, drowsiness, fainting.
- Common cold.

Less frequent side effects:

- Bruising.

- Dehydration (loss of body fluids).
- Restlessness, nervousness.
- Vertigo (a sensation of spinning or swaying).
- 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, irritability, confusion, fits.
- Blurred vision, eye irritation.
- Hot flushes, changes in blood pressure.
- Stomach ulcers, constipation, bloating, abdominal pain, blood in the stools, excessive salivation.
- Itchy rash, unusual sweating.
- Painful joints, bone fractures, temporary paralysis or weakness of muscles, accidents including falls.
- Increased sex drive.
- Toothache.
- The need to wake up at night and pass urine (nocturia).

Side effects occurring with an unknown frequency:

- A condition in which there is a decreased number of red blood cells in the body.
- Low sodium levels in the blood.
- 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 or pharmacist. 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

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

5. How to store NEPIZEL

- Store at or below 25 °C.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton / blister strip.
- Keep the blister strips in the outer carton until required for use.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What NEPIZEL contains

The active substance in NEPIZEL is donepezil hydrochloride.

Each NEPIZEL 5 film coated tablet contains 5 mg donepezil hydrochloride.

Each NEPIZEL 10 film coated tablet contains 10 mg donepezil hydrochloride.

The other ingredients are croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, Opadry (macrogol, talc, titanium dioxide [E171] [colourant]).

NEPIZEL 10 also contains iron oxide yellow (E172) (colourant).

What NEPIZEL looks like and contents of the pack

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

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

Transparent PVC/PVDC/silver aluminium foil blister strips of 10 tablets each, packed into an outer carton.

Pack size: 30 tablets.

Holder of certificate of registration

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