Scheduling status: **S5**

DONECEPT ODT

(Donepezil 5 mg and 10 mg orally disintegrating tablets)

Contains sugar: Lactose Monohydrate 131.25 mg (5 mg) and 262.5 mg (10 mg) per tablet

Contains sweetener: Aspartame 5 mg (5 mg) and 10 mg (10 mg) per tablet

Read all of this leaflet carefully before you start taking DONECEPT ODT.

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

1. What DONECEPT ODT is and what it is used for

DONECEPT ODT contains an ingredient called donepezil hydrochloride.

DONECEPT ODT is used to treat a decline in memory (dementia) associated with Alzheimer's disease.

2. What you need to know before you take DONECEPT ODT

Do not take DONECEPT ODT if:

- You are hypersensitive to the active ingredient (donepezil hydrochloride), or any of the other ingredients of DONECEPT ODT (listed in **section 6**).
- You are a child or adolescent below 18 years of age.

Warnings and precautions:

Take special care with DONECEPT ODT:

- If you will undergo anaesthesia.
- If you have been diagnosed with any heart condition (such as irregular or very slow heart beat, heart failure, myocardial infarction).
- If you have a heart condition called 'prolonged QT interval' or a history of certain abnormal heart rhythms called Torsade de Pointes or if anyone in your family have 'prolonged QT interval'
- If you have low levels of magnesium or potassium in your blood
- If you have a history of ulcer disease (stomach ulcers) or if you are taking any medicines for inflammation.
- If you have been diagnosed with a blockage (obstruction) of the bladder.
- If you have seizures (fits)
- If you experience abnormally high body temperatures, muscle stiffness, altered consciousness and elevation of an enzyme called creatine phosphokinase (determined by laboratory tests).
- If you have been diagnosed with asthma or obstructive pulmonary disease.

You must tell your doctor if you have any of the conditions or health problems listed above before taking DONECEPT ODT**.**

Children and adolescents (under 18 years of age)

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

Other medicines and DONECEPT ODT

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

The following medicines may increase the effect of DONECEPT ODT, you must tell your doctor if you are taking any of them while being treated with DONECEPT ODT:

- Ketoconazole and itraconazole: used to treat fungal infections.
- Quinidine, amiodarone and sotalol: used to treat heart conditions.
- Erythromycin, clarithromycin, levofloxacin and moxifloxacin: ~~an~~ antibiotic's used to treat bacterial infections.
- Citalopram, escitalopram and amitriptyline: medicines used to treat depression
- Pimozide, sertindole and ziprasidone: medicines for psychosis

The following medicines may decrease the effect of DONECEPT ODT, you must tell your doctor if you are taking any of them while being treated with DONECEPT ODT:

- Phenytoin, carbamazepine and phenobarbitone: used to treat or prevent seizures.
- Dexamethasone: used to treat inflammatory conditions such as arthritis.
- Rifampicin: used to treat tuberculosis (TB).

Alcohol could also decrease the effect of DONECEPT ODT

Tell your doctor if you are also taking any of the following medicines while being treated with DONECEPT ODT:

- Medicines which fall under a class called anticholinergics such as atropine or ipratropium bromide.
- Medicines which fall under a class called cholinomimetics such as pilocarpine or physostigmine.

Ask your doctor, pharmacist or health care provider if you are not certain which medicines fall under the above classes.

Taking DONECEPT ODT with any of these above listed medicines increases the incidence of undesirable effects associated with these other medicines.

DONECEPT ODT with food, drink and alcohol

DONECEPT ODT can be taken with or without food.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care provider for advice before taking DONECEPT ODT.

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

Driving and using machines

Memory loss (Dementia) may affect your driving and ability to use machines. Furthermore, DONECEPT ODT may cause sleepiness, dizziness and muscle cramps which may also affect your ability to drive or use machines.

Ensure that you do not engage in the above activities until you are aware of the extent to which DONECEPT ODT affects you.

Important information about some of the ingredients of *DONECEPT ODT*

DONECEPT ODT contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your health care professional before taking DONECEPT ODT.

DONECEPT ODT contains aspartame. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly. Contact your health care provider before taking DONECEPT ODT.

3. How to take DONECEPT ODT

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

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

The usual dose is 1 tablet, taken as a single dose with or without food.

Place the tablet on your tongue and allow it to disintegrate before swallowing with or without water.

Do not crush or break the tablets.

Your doctor will tell you how long your treatment with DONECEPT ODT will last. Do not stop treatment early.

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

If you take more DONECEPT ODT than you should

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

The signs and symptoms associated with an overdose of DONECEPT ODT are:

- Nausea
- Vomiting
- Sweating
- Slow heart rate
- Low blood pressure
- Difficulty breathing,
- Collapse
- Convulsions (fits)

If you forget to take DONECEPT ODT

Do not take a double dose to make up for the forgotten individual doses. If you forget to take DONECEPT ODT, please take your next usual dose the following day.

If you stop taking DONECEPT ODT

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

4. Possible side effects

DONECEPT ODT can have side effects.

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

If any of the following happens, stop taking DONECEPT ODT and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reactions such as a rash or itching; swelling of face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing.
- Abnormally high body temperature, muscle stiffness and altered consciousness.

These are all very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Common cold or influenza symptoms,
- An eating disorder called anorexia,
- Abnormal dreams and nightmares,
- Agitation,
- Unrealistic beliefs or impressions (delusions),
- Depression,
- Hallucinations,
- Sleeplessness (insomnia),
- Headache,
- Dizziness,
- Sleepiness,
- Stomach (abdominal) disturbance,

- Diarrhoea,
- Nausea,
- Vomiting,
- Muscle cramps
- Frequent urination,
- Tiredness,
- Pain,
- Weight loss,

Less frequent side effects:

- Dehydration,
- Abnormal crying,
- Aggressive behaviour,
- Increased sexual desire (libido),
- Irritability,
- Nervousness,
- Restlessness,
- Impact on ability to communicate (aphasia),
- Impaired balance or coordination (ataxia),
- Tingling sensation in the hands and/or feet,
- Fainting,
- Seizures (fits),
- Eye cataracts,
- Eye irritation,

- Blurred vision,
- A spinning sensation (vertigo),
- Hot flushes,
- High blood pressure,
- Dilation of the blood vessels,
- Low blood pressure,
- Shortness of breath,
- Sore throat,
- Bloating
- Pain or discomfort in your upper abdomen,
- Blood in the stool,
- Toothache,
- Increased salivation,
- A liver condition called hepatitis,
- Sweating,
- Discoloration of the skin,
- Muscle weakness,
- Frequent urination at night,
- Chest pain,
- Increases in creatine kinase in your blood (determined by laboratory tests),
- Accidents and bone fractures.

Frequency not known (frequency cannot be estimated from the available data):

- changes in the heart activity which can be seen on an electro-cardiogram (ECG) called 'prolonged QT interval'
- fast, irregular heart beat, fainting which could be symptoms of a life-threatening condition known as Torsade de Pointes.

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 via email to Cipla Medpro (Pty) Ltd: drugsafety@cipla.com. By reporting side effects, you can help provide more information on the safety of DONECEPT ODT.

5. How to store *DONECEPT ODT*

Store all medicines out of reach of children.

Store in the original container at or below 30 °C.

Do not use after the expiry date stated on the label.

6. Contents of the pack and other information

What DONECEPT ODT contains:

DONECEPT ODT 5: Each orally disintegrating tablet contains donepezil hydrochloride 5 mg as the active ingredient.

DONECEPT ODT 10: Each orally disintegrating tablet contains donepezil hydrochloride 10 mg as the active ingredient.

The other ingredients are aspartame, croscarmellose sodium, lactose monohydrate (spray dried), magnesium stearate, microcrystalline cellulose, monosodium citrate anhydrous, polacrilin potassium and silica (colloidal anhydrous).

What DONECEPT ODT looks like and contents of the pack

DONECEPT ODT 5: White to off-white round, flat tablets with bevelled edges, embossed with '5' on one side and plain on the other.

DONECEPT ODT 10: White to off-white round, flat tablets with bevelled edges, embossed with '10' on one side and plain on the other.

DONECEPT ODT 5 and 10 mg orally disintegrating tablets are packed in transparent PVC/PCTFE/ Aluminum blisters or Aluminum/Aluminum blisters, which are subsequently packed into cardboard boxes**.**

Holder of certificate of registration

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This leaflet was last revised in:

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Registration number(s):

DONECEPT ODT 5: 53/5.3/0046

DONECEPT ODT 10: 53/5.3/0047

Access to the corresponding professional information:

The corresponding professional information can be found in the packaging of this medicine.

PLACE HOLDER: The QR Code to be generated and included after approval.