PROPOSED PATIENT INFORMATION LEAFLET (Clean copy)

Read all of this leaflet carefully before you start taking [PRODUCT NAME] TABLETS.

- Keep this leaflet. You may need to read it again.

- If you have further questions, please ask your doctor or your pharmacist.

- **[PRODUCT NAME] TABLETS** have 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.

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[PRODUCT NAME] 5 mg TABLETS (Tablet)

[PRODUCT NAME] 10 mg TABLETS (Tablet)

Donepezil hydrochloride

1. WHAT [PRODUCT NAME] TABLETS CONTAIN

The active substance is donepezil hydrochloride.

[PRODUCT NAME] 5 mg TABLETS:

Each film-coated tablet contains donepezil hydrochloride 5 mg.

[PRODUCT NAME] 10 mg TABLETS:

Each film-coated tablet contains donepezil hydrochloride 10 mg.

The other ingredients of **[PRODUCT NAME] TABLETS** are hypromellose, lactose monohydrate, hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, talc and titanium dioxide. **[PRODUCT NAME] 10 mg TABLETS** also contains iron oxide yellow.

2. WHAT [PRODUCT NAME] TABLETS ARE USED FOR

[PRODUCT NAME] TABLETS belongs to a group of medicines called acetylcholinesterase inhibitors.

[PRODUCT NAME] TABLETS are used to treat mild to moderate dementia (a brain disorder that affects the ability to remember, think clearly, communicate, and perform daily activities and may cause changes in mood and personality) caused by Alzheimer's disease.

3. BEFORE YOU TAKE [PRODUCT NAME] TABLETS

Do not take [PRODUCT NAME] TABLETS:

- If you are hypersensitive (allergic) to donepezil hydrochloride, piperidine derivatives or any of the other ingredients of **[PRODUCT NAME] TABLETS**.
- In children – Because the safety and effectiveness of **[PRODUCT NAME] TABLETS** has not been established in children. **[PRODUCT NAME] TABLETS** should not be given to children.

Take special care with [PRODUCT NAME] TABLETS:

- The use of **[PRODUCT NAME] TABLETS** in patients with severe dementia, other types of dementia or other types of memory problems has not been determined.

Before taking [PRODUCT NAME] TABLETS, tell your doctor if you have or have had:

- “sick sinus syndrome” which may present with symptoms such as chest pain, shortness of breath, dizziness, fatigue, nausea, fainting or a fast heartbeat, or other heart disease.
- gastrointestinal (affecting the stomach and intestines) bleeding, ulcers, or if you are taking non-steroidal anti-inflammatory medicines (NSAIDs).
- seizures (fits) or convulsions.
- asthma or other obstructive lung disease.
- difficulty passing urine.
- If you are having surgery, including dental surgery, tell the doctor or dentist that you are taking **[PRODUCT NAME] TABLETS**.
- If you are recovering from recent bladder or gastrointestinal surgery.

Taking [PRODUCT NAME] TABLETS with food and drink:

[PRODUCT NAME] TABLETS can be taken with or without food.

Alcohol may change the effect of **[PRODUCT NAME] TABLETS** as the rate that **[PRODUCT NAME] TABLETS** is eliminated from your system is increased therefore decreasing the duration that **[PRODUCT NAME] TABLETS** may work for you.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby while taking [PRODUCT NAME] TABLETS, please consult your doctor, pharmacist or other health care professional for advice.

The safe use of **[PRODUCT NAME] TABLETS** during pregnancy and while breastfeeding your baby has not been established.

Driving and using machinery:

Dementia may impair your ability to drive or operate machinery. Also, **[PRODUCT NAME] TABLETS** can cause tiredness, dizziness and muscle cramps, especially when starting or increasing the dose. You must not drive or operate machinery unless your doctor tells you that it is safe to do so.

Important information about some of the ingredients of [PRODUCT NAME] TABLETS:

[PRODUCT NAME] TABLETS contain lactose therefore if you are lactose intolerant or have a history of galactose intolerance, Lapp-lactose deficiency or glucose-galactose malabsorption.

Taking other medicines with [PRODUCT NAME] TABLETS:

Before taking **[PRODUCT NAME] TABLETS**, tell your doctor if you are using any of the following medicines:

- pain killers or treatment for arthritis e.g. non-steroidal anti-inflammatory medicines (NSAIDs) such as ibuprofen or diclofenac sodium
- antibiotics e.g. erythromycin, rifampicin
- anti-fungal medicines e.g. ketoconazole, itraconazole
- anti-depressants e.g. fluoxetine
- anticonvulsants e.g. phenytoin, carbamazepine, phenobarbital
- medication for a heart condition e.g. quinidine
- corticosteroids e.g. dexamethasone
- muscle relaxants e.g. succinylcholine

- general anaesthetic – If you are going to have an operation that requires you to have a general anaesthetic, you should tell your doctor or anaesthetist that you are taking **[PRODUCT NAME] TABLETS.**

If you are using any of the above medicines, you may not be able to take **[PRODUCT NAME] TABLETS**, or you may need dosage adjustments or your doctor may need to monitor you carefully for side-effects.

4. HOW TO TAKE [PRODUCT NAME] TABLETS

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **[PRODUCT NAME] TABLETS** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

Always take **[PRODUCT NAME] TABLETS** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **[PRODUCT NAME] TABLETS** is too strong or too weak, talk to your doctor or pharmacist.

Adults and the elderly:

- The usual starting dose is 5 mg once a day.
- After one month, your doctor may increase your dose to 10 mg once a day.
- The maximum recommended dose is 10 mg once a day.
- The dose is similar for patients with kidney disease or mild to moderate liver disease.

If you take more [PRODUCT NAME] TABLETS than you should:

Symptoms of overdose may include nausea and vomiting, drooling, sweating, slow heart rate, low blood pressure, breathing problems, losing consciousness and seizures (fits).

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

If you forget to take [PRODUCT NAME] TABLETS:

Take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the medicine at your next regularly scheduled time. Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE-EFFECTS

[PRODUCT NAME] TABLETS can have side-effects.

Get emergency medical help if you have any of these signs of an allergic reaction:

- Hives, difficulty breathing, swelling of your face, lips, tongue, or throat.

Call your doctor at once if you have any of these serious side-effects:

- seizures (fits) or convulsions
- slow heartbeat
- fainting
- black, bloody, or tarry stools
- coughing up blood or vomit that looks like blood or coffee grounds
- chest pain
- hepatitis (inflammation of the liver). The symptoms of hepatitis are nausea or vomiting, loss of appetite; feeling generally unwell; fever; itching; yellowing of the skin and eyes; and dark coloured urine.

Other side-effects include: the common cold; flu; excessive loss of body water; inability to sleep; abnormal dreams; being agitated; depression; abnormal crying; aggressive behaviour; increased sexual desire; nervousness; restlessness; hallucinations (seeing or hearing things that are not really there); dizziness; headache; sleepiness; language disorder; loss of muscle co-ordination; numbness, tingling, pins and needles; tremor (shake); decrease in vision due to clouding of the lens of the eye; eye irritation; blurred vision; hot flushes; high blood pressure; low blood pressure; shortness of breath; sore throat; diarrhoea (frequent or loose watery stools); lack of appetite; stomach pain; abnormal swelling due to a collection of gas or fluid in your abdomen, toothache; stomach ulcer; duodenal ulcer (ulcer in the duodenum); increased sweating; itching; muscle cramps; passing urine frequently;

inability to control urination; infection of the urinary tract; extreme tiredness; pain; loss of weight; accidents; bone fractures.

Tell your doctor if any of the above side-effects are severe, bothersome, do not go away or about any other concerns you have while taking **[PRODUCT NAME] TABLETS**.

Not all side-effects reported for **[PRODUCT NAME] TABLETS** are included in this leaflet. Should your general health worsen while taking **[PRODUCT NAME] TABLETS**, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF [PRODUCT NAME] TABLETS

Store at or below 25 ºC. Protect from light. Do not remove blisters from carton until required for use.

Keep securitainer well-closed after use.

Keep all medicines out of the reach and sight of children.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF [PRODUCT NAME] TABLETS

[PRODUCT NAME] 5 mg TABLETS:

1) Blister Pack:

Tablets are packed in 250 micron clear PVC/25 micron PE/90 gsm PVdC and silver coloured printed 25 micron aluminium foil with 7 gsm heat seal lacquer.

Each blister contains 10 tablets.

Pack size: 30's – Each carton contains 3 blisters of 10 tablets each.

2) HDPE Container Pack:

Tablets are packed in 40 ml HDPE white container with white closure with induction sealing wad containing 1 No. of 1 gm silica gel sachet.

Each container contains 30 tablets.

Pack size: 30's - One HDPE container contains 30 tablets.

[PRODUCT NAME] 10 mg TABLETS:

1) Blister Pack:

Tablets are packed in 250 micron clear PVC/25 micron PE/90 gsm PVdC and silver cloured printed 25 micron aluminium foil with 7 gsm heat seal lacquer.

Each blister contains 10 tablets.

Pack size: 30's – Each carton contains 3 blisters of 10 tablets each.

2) HDPE Container Pack:

Tablets are packed in 40 ml HDPE white container with white closure with induction sealing wad containing 1 No. of 1 gm silica gel sachet.

Each container contains 30 tablets.

Pack size: 30's - One HDPE container contains 30 tablets.

8. IDENTIFICATION OF [PRODUCT NAME] TABLETS

[PRODUCT NAME] 5 mg TABLETS

White to off-white, circular, biconvex, film-coated tablets debossed with 'X' on one side and '11' on the other side.

[PRODUCT NAME] 10 mg TABLETS

Yellow coloured, circular, biconvex, film-coated tablets debossed with 'X' on one side and '12' on the other side.

9. REGISTRATION NUMBER/REFERENCE NUMBER

PRIFET 5 mg TABLETS: 44/5.3/0946

PRIFET 10 mg TABLETS: 44/5.3/0947

NELOPT 5 mg TABLETS: 44/5.3/0942

NELOPT 10 mg TABLETS: 44/5.3/0943

ZEPANALZ 5 mg TABLETS: 44/5.3/0944

ZEPANALZ 5 mg TABLETS: 44/5.3/0945

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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