

APPROVED PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking PRIFET TABLETS.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **PRIFET 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.

S5

PRIFET 5 mg TABLETS (Tablet)

PRIFET 10 mg TABLETS (Tablet)

Donepezil hydrochloride

1. WHAT PRIFET TABLETS CONTAIN

The active substance is donepezil hydrochloride.

PRIFET 5 mg TABLETS:

Each film-coated tablet contains donepezil hydrochloride 5 mg.

PRIFET 10 mg TABLETS:

Each film-coated tablet contains donepezil hydrochloride 10 mg.

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

2. WHAT PRIFET TABLETS ARE USED FOR

PRIFET TABLETS belongs to a group of medicines called acetylcholinesterase inhibitors.

PRIFET 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 PRIFET TABLETS

Do not take PRIFET TABLETS:

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

Take special care with PRIFET TABLETS:

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

Before taking PRIFET 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 **PRIFET TABLETS**.
- If you are recovering from recent bladder or gastrointestinal surgery.

Taking PRIFET TABLETS with food and drink:

PRIFET TABLETS can be taken with or without food.

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

Pregnancy and Breastfeeding:

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

The safe use of **PRIFET 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, **PRIFET 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 PRIFET TABLETS:

PRIFET 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 PRIFET TABLETS:

Before taking **PRIFET 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 **PRIFET**

TABLETS.

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

4. HOW TO TAKE PRIFET TABLETS

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

Always take **PRIFET 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 **PRIFET 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 PRIFET 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 PRIFET 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

PRIFET 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 **PRIFET TABLETS**.

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

6. STORING AND DISPOSING OF PRIFET TABLETS

Store at or below 25 °C. 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 PRIFET TABLETS

PRIFET 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.

PRIFET 10 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.

8. IDENTIFICATION OF PRIFET TABLETS

PRIFET 5 mg TABLETS

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

PRIFET 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

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Aurogen South Africa (Pty) Ltd
Woodhill Office Park, Building 1,
53 Phillip Engelbrecht Avenue
Meyersdal, Ext. 12, 1448
Johannesburg
South Africa

11. DATE OF PUBLICATION

Date of registration:

20 June 2013

Date of revision:

18 September 2021