PATIENT INFORMATION LEAFLET FOR ALZIDO 5 mg / 10 mg

SCHEDULING STATUS

Schedule 5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

ALZIDO 5 mg (film coated tablets)

ALZIDO 10 mg (film coated tablets)

Please read this leaflet carefully before taking ALZIDO tablets

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

1. WHAT ALZIDO CONTAINS

Active ingredient

Each **ALZIDO 5 mg** film coated tablet contains 5 mg donepezil hydrochloride

Each **ALZIDO 10 mg** film coated tablet contains 10 mg donepezil hydrochloride

Inactive ingredients

Hydroxypropylcellulose, lactose monohydrate, magnesium stearate, maize starch, microcrystalline cellulose, Opadry White (containing hypromellose, titanium dioxide, macrogol and talc).

2. WHAT ALZIDO IS USED FOR

ALZIDO is used to treat mild to moderate dementia in Alzheimer's disease.

3. BEFORE YOU TAKE ALZIDO

Do not take ALZIDO:

- If you are hypersensitive (allergic) to donepezil hydrochloride, piperidine derivatives or to any of the ingredients of **ALZIDO** (see **WHAT ALZIDO CONTAINS**).
- If you are recovering from a bladder or stomach operation.
- If you are pregnant or breastfeeding (see **Pregnancy and breastfeeding**).
- **Children should not take ALZIDO**.

Take special care with ALZIDO:

- 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 disease such as asthma.

Regular visits to your doctor may be necessary to determine if the treatment is still effective.

Inform your doctor, surgeon or anaesthesiologist that you are using **ALZIDO** before undergoing surgery.

Since **ALZIDO** is associated with weight loss, your weight should be regularly monitored.

If you are a female, you may be more susceptible to weight loss, nausea, vomiting and anorexia.

Taking ALZIDO with food and drink:

ALZIDO can be taken with or without food or drink.

Pregnancy and breastfeeding:

Do not use **ALZIDO** if you are pregnant, planning to become pregnant or breastfeeding. Consult your doctor.

Driving and using machinery:

ALZIDO may make you drowsy and impair your ability to drive or use machinery. Take care until you know how **ALZIDO** affects you.

Important information about some of the ingredients of ALZIDO:

ALZIDO contains lactose, which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (you have an intolerance to some sugars), talk to your doctor before taking **ALZIDO**.

Using other medicines with ALZIDO:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **ALZIDO** with these medicines may cause undesirable interactions. Tell your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop. Please consult your doctor, pharmacist or other healthcare professional for advice before taking any other medicines.

The following medicines may interact with **ALZIDO** and cause undesirable side effects:

dexamethasone (used in conditions with inflammation), non-steroidal 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) and medicines used in the treatment of tuberculosis/TB (e.g. rifampicin).

4. HOW TO TAKE ALZIDO TABLETS

Take **ALZIDO** exactly as prescribed by your doctor. You should check with your doctor or pharmacist if you are not sure.

Do not give **ALZIDO** to another person or to any child of any age even if their symptoms appear to be the same.

Take one **ALZIDO 5 mg** tablet every day in the evening just before you go to bed. Your doctor may increase your dose to one **ALZIDO 10 mg** tablet should it be necessary.

If you take more ALZIDO than you should:

In case of an accidental or intentional overdose contact your doctor or pharmacist as soon as possible. If neither is available, seek help at 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 ALZIDO:

If you miss a dose of **ALZIDO**, take it as soon as you remember. Do not take **ALZIDO** 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 **ALZIDO** to make up for a missed dose.

5. POSSIBLE SIDE EFFECTS

ALZIDO may have side effects.

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

Should your general health worsen while taking ALZIDO, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **ALZIDO** and tell your doctor immediately or go to the casualty department at your nearest hospital.

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **ALZIDO**. 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,
- angina,
- changes in the way your heart beats, for example, if you notice it beating faster or if it is beating irregularly,
- difficulty breathing.

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:

- Diarrhoea, nausea, vomiting, loss of appetite, heartburn, weight loss, involuntary loss of bowel contents
- Muscle cramps
- Sleep disorders, tiredness, agitation
- General pain, abdominal pain or headache
- Dizziness, abnormal dreams
- Frequent urination or inability to control urination
- Sweating, rash
- Loosing sense of reality (seeing and hearing things that is not there).

Tell your doctor if you notice any of the following less frequent side effects:

- Mood disorders, depression, restlessness, nervousness, irritability, abnormal crying, confusion
- Eye disorders
- Hot flushes, changes in blood pressure
- Unusual bleeding or bruising, constipation, bloating, toothache, stomach or gastric ulcers
- Pins and needles feeling in your hands and feet, tremors

- Dryness
- Bone fracture
- Increased libido (sex drive).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

If any of these side effects persist or worsen, please inform your doctor as soon as possible.

6. STORING AND DISPOSING OF ALZIDO

- Store in a dry place at or below 25 °C.
- Keep the blisters in the outer carton until required for use.
- **KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN**
- Do not use the film coated tablets after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF ALZIDO

Clear PVDC/PVC/silver aluminium foil blister strips of 14 tablets each. Two (2) blister strips of 14 tablets each are packed into an outer carton.

8. IDENTIFICATION OF ALZIDO

ALZIDO 5 mg: White to off white, round shaped, biconvex film coated tablets debossed with ‘ZF9’ on one side and plain on the other side.

ALZIDO 10 mg: White to off white, round shaped, biconvex film coated tablets debossed with ‘ZF10’ on one side and plain on the other side.

9. REGISTRATION NUMBERS

ALZIDO 5 mg: 45/5.3/0939

ALZIDO 10 mg: 45/5.3/0940

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Zydus Healthcare SA (Pty) Ltd

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11. DATE OF PUBLICATION

05 December 2013