PATIENT INFORMATION LEAFLET

Scheduling Status: S5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

ARICEPT® 5 mg Tablets (Donepezil Hydrochloride)

ARICEPT® 10 mg Tablets (Donepezil Hydrochloride)

Read this leaflet carefully before you start using this medicine

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

The active ingredient of ARICEPT is donepezil hydrochloride. ARICEPT tablets contain the following inactive ingredients: hydroxypropyl cellulose, lactose monohydrate, maize starch, microcrystalline cellulose and magnesium stearate. The film coating contains hydroxypropyl methycellulose, polyethylene glycol, talc and titanium dioxide. Additionally, the 10 mg tablet contains yellow iron oxide (synthetic) as a colouring agent.

WHAT ARICEPT® IS USED FOR

ARICEPT tablets are used to treat the symptoms of dementia in people diagnosed as having Alzheimer's Disease.

BEFORE YOU TAKE ARICEPT TABLETS

Do not use ARICEPT:

If you are allergic to any of the ingredients listed above

Take special care with and tell your doctor or pharmacist:

- If you have had a stomach ulcer in the past
- If you often take medicine for pain
- If you are pregnant, think you might be pregnant or are breast feeding
- If you have had a seizure(s) or a heart condition in the past
- If you have asthma or other long-term lung disease
- If you have difficulty in trying to urinate
- If you plan to go to the hospital for an operation that requires you to have a general anaesthetic.

Taking other medicines

Always tell your healthcare professional if you taking any other medicine (This includes complimentary or traditional medicines)

Especially:

- pain killers or treatment for arthritis
- antibiotics
- anti-fungal medicine
- anti-depressants
- anticonvulsants
- medication for a heart condition
- muscle relaxants

If in doubt, consult your doctor or pharmacist before taking ARICEPT tablets.

Tell your doctor or pharmacist the name of your caregiver. Your caregiver will help you to take your medicine as it is prescribed.

Your ability to drive or use machinery may be affected by your illness. Furthermore, your medicine can cause fatigue, dizziness and muscle cramps, mainly when starting or increasing the dose. Therefore your ability to perform these tasks should be regularly checked by your doctor.

HOW TO TAKE ARICEPT TABLETS

Always take ARICEPT exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are unsure. Take your ARICEPT tablet by mouth with a drink of water at night before you go to bed. Usually, you will start by taking one 5 mg (white tablet) tablet every night. After one month, your doctor may tell you to take one 10 mg (yellow tablet) tablet every night. The maximum recommended dose is 10 mg each night.

Do not alter the dose yourself without your doctor's advice. Do not stop taking the tablets unless told to do so by your doctor.

If you take more ARICEPT than you should:

DO NOT take more than one tablet each day. These are the possible signs and symptoms of overdosage: severe nausea, vomiting, sweating, increased saliva, low blood pressure, difficulty with breathing, convulsions.

Call your doctor immediately if you take more tablets than you should. If you cannot call your doctor go to the nearest hospital or poison control centre at once.

If you forget to take ARICEPT:

If you forget to take a tablet, just take one tablet the following day at the usual time. If you forget to take your medicine for more than one week, call your doctor before taking any more medicine.

How quickly will the treatment start to work

Improvements may be seen in three weeks of starting treatment in those patients who respond, although patients' responses vary. Your doctor may need to assess your condition from time to time.

POSSIBLE SIDE-EFFECTS

ARICEPT can have side-effects. There have been reports of diarrhoea, muscle cramps, tiredness, nausea, vomiting, difficulty getting to sleep, dizziness, headache, pain, accident, common cold, occurring during treatment with ARICEPT tablets. In most cases, these went away without having to

stop treatment. Tell your doctor if you have any of these effects and if they are too uncomfortable for you. During treatment there have also been reports of hallucination, agitation, aggressive behaviour, seizure, hepatitis and abdominal disturbances including bleeding, stomach and duodenal ulcers, syncope (fainting), bradycardia (slow heart beat) and rarely heart block (which may cause dizziness and fainting).

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while or if you experience any untoward effects while taking this ARICEPT tablets, please consult your doctor, pharmacist or other health care professional for advice.

STORING AND DISPOSING OF ARICEPT

Keep all medicines out of reach and sight of children. This medicine should be kept at room temperature. Store below 30^0C. This medicine is for you. Only a doctor can prescribe it for you. Do not share it with anyone else. It may harm them, even if they have the same symptoms as you.

DO NOT use ARICEPT tablets after the expiry date which is printed on the label. Return all unused medicine to your pharmacist. DO NOT dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION

ARICEPT tablets come in blister strips 28.

IDENTIFICATION

ARICEPT 5 mg: White, round, biconvex, film-coated tablets embossed with the word “ARICEPT” on the one side and “5” on the other side

ARICEPT 10 mg: Yellow, round, biconvex, film-coated tablets embossed with the word “ARICEPT” on the one side and “10” on the other side

REGISTRATION NUMBER / REFERENCE NUMBER

ARICEPT 5 mg tablets: 32/5.3/0315

ARICEPT 10 mg tablets: 32/5.3/0316

NAME AND ADDRESS OF REGISTRATION HOLDER

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

SANDTON, 2196

DATE OF PUBLICATION

1. Last Council Approval: 10 October 2008
2. Compliance with regulation 9 & 10: 15 February 2017