PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

PROPRIETARY NAME AND DOSAGE FORM

ARIMENTIA 5 mg

ARIMENTIA 10 mg

Film-coated tablet

Read all of this leaflet carefully before you start taking ARIMENTIA

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

The active substance in each film-coated tablet of ARIMENTIA 5 mg is 5 mg donepezil hydrochloride.

The other ingredients are:

Hydroxypropylcellulose, lactose monohydrate, magnesium stearate, maize starch, microcrystalline cellulose, polyethylene glycol, titanium dioxide (C.I. 77891)

Contains sugar: Lactose monohydrate 91,75 mg

The active substance in each film-coated tablet of ARIMENTIA 10 mg is 10 mg donepezil hydrochloride.

The other ingredients are:

Hydroxypropylcellulose, lactose monohydrate, magnesium stearate, maize starch, microcrystalline cellulose, polyethylene glycol, titanium dioxide (C.I. 77891)

Contains sugar: Lactose monohydrate 183,5 mg

WHAT ARIMENTIA IS USED FOR

ARIMENTIA belongs to a group of medicines called Cholinomimetics (cholinergics). ARIMENTIA is used for the symptomatic treatment of mild or moderate dementia in Alzheimer's disease.

BEFORE YOU TAKE ARIMENTIA

Do not take ARIMENTIA if:

- You are hypersensitive (allergic) to donepezil, piperidine derivatives or any of the other ingredients of ARIMENTIA.
- You are pregnant or breastfeeding.
- You are a child.

Take special care with ARIMENTIA

- If you are going to be given anaesthetics.
- If you have a heart condition.
- If you have a history of ulcer disease.
- If you are taking any medication for pain or inflammation that is a nonsteroidal anti-inflammatory drug (NSAID).

- If you experience diarrhoea, nausea and vomiting for a prolonged time.
- If you have difficulty urinating or if you have a blockage that stops the flow of urine through its normal path.
- If you have recurrent fits.
- If you have asthma.
- If you have obstructive pulmonary disease.
- If you develop a high fever, uneven pulse, increased heartbeat, increased breathing, muscle rigidity and mental deterioration which are symptoms of a disease called neuroleptic malignant syndrome.
- If you consume excessive quantities of alcohol.

Pregnancy and breastfeeding

You should not take ARIMENTIA if you are pregnant or breastfeeding your baby.

Always tell your healthcare provider if you are taking any other medicine. If you are pregnant or breastfeeding your baby please consult your healthcare provider for advice before taking ARIMENTIA.

Driving and using machinery

Since adverse reactions such as dizziness, sleepiness and blurred vision have been reported in patients receiving ARIMENTIA, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that ARIMENTIA does not adversely affect your ability to do so (see POSSIBLE SIDE EFFECTS).

Important information about some of the ingredients in ARIMENTIA

ARIMENTIA contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take ARIMENTIA.

Taking other medicines with ARIMENTIA

Always tell your healthcare provider if you are taking any other medicines (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- Ketoconazole, itraconazole, used to treat fungal infections.
- Erythromycin, medicine used to treat bacterial infections.
- Quinidine, used to treat or prevent many types of irregular heartbeats.
- Anticonvulsants (e.g. phenytoin, carbamazepine), used to treat seizures (fits) and nerve pain.
- Dexamethasone (corticosteroid), used to treat many different conditions such as allergic disorders, skin conditions etc.
- Rifampicin, used to treat tuberculosis (TB).
- Phenobarbitone, used to to treat fits (epilepsy).
- Anticholinergic medications, used to treat gastrointestinal diseases, motion sickness, incontinence, Parkinson’s disease etc.
- Other cholinesterase inhibitors, used to treat Alzheimer's disease.
- Succinylcholine or similar neuromuscular blocking medicine or cholinergic agonists like bethanechol, used to treat urinary retention (difficulty urinating).
- Beta-blockers, medicine used to treat irregular heartbeats, angina and high blood pressure. Fluoxetine, used to treat depression.

HOW TO TAKE ARIMENTIA

Always take ARIMENTIA as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Do not share medicines prescribed for you with any other person.

The usual dose is:

The starting dose is 5 mg a day, taken orally in the evening, just before bed-time. This dose is usually continued for up to a month.

After one month and after a check-up, the dose may be increased to 10 mg a day.

Your doctor will tell you how long your treatment with ARIMENTIA will last.

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

If you take more ARIMENTIA than you should

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

You may experience the following:

Reduced spontaneous movement, staggered walking, lower body surface temperature, severe nausea, vomiting, salivation, sweating, abnormally slow pulse rate, low blood pressure, abnormally slow and/or shallow breathing, collapse, fits, increasing muscle weakness including breathing muscles.

Atropine can be used as a remedy and treatment is also supportive.

If you forget to take/missed a dose of ARIMENTIA

Take your missed dose as soon as you remember, if within a few hours after missing a dose. Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS

ARIMENTIA can have side effects.

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

If any of the following happens, stop taking ARIMENTIA 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.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ARIMENTIA. 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:

- Internal bleeding of the stomach or intestine;
- stomach or small intestine (duodenal) ulcers;
- chest pain;
- fits;
- unusual bleeding or bruising known as ecchymosis;
- abnormally slow pulse rate (heart block);
- irregular and often rapid heart rate;
- difficulty in breathing;
- inflammation of the liver, liver disease;

- difficulty urinating (a blockage that stops the flow of urine through its normal path);
- abnormal muscle breakdown which can lead to kidney problem;
- high fever, uneven pulse, accelerated heartbeat, increased breathing, muscle rigidity and mental deterioration which are symptoms of a disease called neuroleptic malignant syndrome.

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

The following side effects have been frequently reported:

- Lack of appetite, weight loss;
- sleeplessness, dizziness, sleepiness, headache, abnormal dreams;
- delusions, nightmares, depression, hallucinations, agitation;
- nausea, diarrhoea, vomiting, heartburn or indigestion, bowel control problems, frequent urination;
- muscle cramps;
- bone fracture, accident;
- bladder infection;
- itching;
- tiredness, influenza, common cold, toothache, pain (in various locations).

The following side effects have been reported less frequently:

- Upper respiratory tract infection;
- bloating, pain in upper or middle region of the stomach, excessive production of saliva, sweating;
- inflammation of the joints;
- high blood pressure, hot flushes, low blood pressure (hypotension), dilatation of blood

vessels;

- fainting, light-headedness and loss of balance (vertigo);
- aggression;
- tremor, irritability, tingling;
- loss of muscle co-ordination, increased sex drive, restlessness, abnormal crying, nervousness, problems with speech;
- dehydration;
- sore throat, inflammation of the air passages of the lung;
- cataract, eye irritation, blurred vision;
- loss of bladder control, increased urge to urinate during the night.

The following side effects have been reported but the frequency is unknown:

- Slight increases in your blood of a liver enzyme called serum creatinine kinase;
- confusion.

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

STORING AND DISPOSING OF ARIMENTIA

Store at or below 25 °C protected from light and moisture.

Keep container tightly closed.

Keep in original packaging until required for use.

Do not store in bathrooms.

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

Return all unused medicine to your pharmacist.

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

STORE ALL MEDICINE OUT OF REACH OF CHILDREN.

PRESENTATION OF ARIMENTIA

7, 10, 14, 28, 30, 56, 60, 84, 98, 100 tablets are packed in a silver polyvinyl chloride/polyvinylidene chloride blister strip sealed with an aluminium foil backing. The blister strips are packed into an outer cardboard carton.

100 or 250 tablets are packed in a white polypropylene container with a polyethylene snap on closure with tear off tamper evident strip.

Not all packs and pack sizes are necessarily marketed.

IDENTIFICATION OF ARIMENTIA

ARIMENTIA 5 mg:

White, film-coated round tablet, with score line on one side and plain on the other side, with a diameter of 7,0 mm to 7,4 mm.

ARIMENTIA 10 mg:

White, film-coated round tablet, with score line on one side and plain on the other side, with a diameter of 9,0 mm to 9,4 mm.

REGISTRATION NUMBER

ARIMENTIA 5 mg: 43/5.3/0487

ARIMENTIA 10 mg: 43/5.3/0488

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead, 2191

Hotline: 0800 122 912

DATE OF PUBLICATION

Date of registration:

ARIMENTIA 5 mg: 30 September 2011

ARIMENTIA 10 mg: 30 September 2011

Date of the most recent amendment to the patient information leaflet as approved by the Authority: 30 September 2011

ZA_ARIMTAB_1109_03

GOEDGEKEURDE PROFESSIONELE INLIGTING VIR MEDISYNE VIR MENSLIKE GEBRUIK

SKEDULERINGSTATUS

S5

EIENDOMSNAAM EN DOSEERVORM

ARIMENTIA 5 mg (filmbedekte tablet)

ARIMENTIA 10 mg (filmbedekte tablet)

SAMESTELLING

Elke filmbedekte tablet ARIMENTIA 5 mg bevat 5 mg donepesielhidrochloried.

Eksipiënte:

Hidroksipropiel sellulose, laktosemonohidraat, magnesiumstearaat, mieliestysel, mikrokristallyne sellulose, poliëtileenglikol, titaandioksied (C.I. 77891)

Bevat suiker: Laktosemonohidraat 91,75 mg

Elke filmbedekte tablet ARIMENTIA 10 mg bevat 10 mg donepesielhidrochloried.

Eksipiënte:

Hidroksipropiel sellulose, laktosemonohidraat, magnesiumstearaat, mieliestysel, mikrokristallyne sellulose, poliëtileenglikol, titaandioksied (C.I. 77891)

Bevat suiker: Laktosemonohidraat 183,5 mg