

PACKAGE LEAFLET: INFORMATION FOR THE USER

Aripez 5 mg Film coated Tablets **Aripez 10 mg Film coated Tablets**

Donepezil hydrochloride

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Aripez is and what it is used for
2. Before you take Aripez
3. How to take Aripez
4. Possible side effects
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6. Further information

1. WHAT ARIPEZ IS AND WHAT IT IS USED FOR

Donepezil belongs to a group of medicines called acetylcholine esterase inhibitors: it increases the levels of the substance acetylcholine in the brain.

It is used to relieve the symptoms of mild to moderate Alzheimer's dementia.

2. BEFORE YOU TAKE ARIPEZ

Remember: You must tell your doctor who your carers are.

Do not take Aripez

- if you are allergic (hypersensitive) to donepezil or any of the other ingredients of Aripez Film-coated Tablets.
- if you are allergic (hypersensitive) to other medicines containing a **piperidine derivative** (Aripez is a piperidine derivative)

Take special care with Aripez

Treatment with Aripez should only be started and supervised by a doctor with experience in diagnosing and treating Alzheimer's dementia.

Inform your doctor if you:

- have ever had a stomach or intestinal ulcer
- frequently take pain-killers or treatment for **rheumatism (pain or inflammation around bones, joints or muscles)**: taking these medicines at the same time as Aripez could put you at greater risk of developing stomach or intestinal ulcers.
- have ever had seizures
- have a heart condition
- have asthma or other long term lung disease
- have difficulties when urinating
- have ever had any liver problems or hepatitis

- are going to have an operation that requires you to have a general anaesthetic. You must inform the anaesthetist that you are taking Aripez .

The individual effect of Aripez cannot be predicted, therefore the effect of the treatment should be evaluated regularly by a doctor.

Aripez is not recommended in children.

Taking other medicines

Inform your doctor if you are being treated with any of the following medicines, because the effect of Aripez or the other medicine could be influenced if you take the two medicines together:

- Medicines against fungal infections, such as ketoconazole or itraconazole
- Antibiotics, such as erythromycin or rifampicin
- Heart medicines, such as quinidine or beta-blockers
- Medicines for epilepsy, such as phenytoin or carbamazepine
- Antidepressants, such as fluoxetine
- Muscle relaxants
- Other medicines that act the same way as Aripez (such as galantamine or rivastigmine), and some medicines for diarrhoea, Parkinson's disease or asthma.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Aripez with food and drink

You must avoid drinking alcohol while you are being treated with Aripez , because it could reduce the effect of Aripez .

Pregnancy and breast-feeding

You must not use Aripez if you are pregnant or breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Alzheimer's disease may impair your ability to drive or operate machinery, and you must not perform these activities unless your doctor tells you that it is safe to do so. Also, your medicine can cause tiredness, dizziness and muscle cramp and if affected, you must not drive or operate machinery.

Important information about some of the ingredients of Aripez

Aripez Film-coated Tablets contain lactose. If you have been told by your doctor that you have **an intolerance to some sugars**, contact your doctor before you take this medicinal product.

3. HOW TO TAKE ARIPEZ

Always take Aripez exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is described below.

You must take Aripez by mouth once daily with a glass of water in the evening just before bedtime.

The tablet strength you will take may change depending on the length of time you have been taking the medicine and on what your doctor will recommend. Usually, you will start by taking 5 mg (one white tablet) every night. After one month, your doctor may tell you to take 10 mg (one yellow) tablet every night. The maximum recommended dose is 10 mg each night.

Both you and your caregivers should be aware of the doctor's instructions.

If you take more Aripez than you should

Contact the doctor immediately if you take too high a dose of Aripez . At a high dose (overdose), the listed side effects may be worse (see section 4: Possible side effects). In particular, severe nausea, vomiting, dribbling, sweating, a slow heart beat, low blood pressure, difficulty breathing, collapse, seizures and muscle weakness may occur.

If you forget to take Aripez

If you forget to take a dose, take it as quickly as possible after noticing this, unless it is time for the next dose.

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Aripez can cause side effects, although not everybody gets them.

Serious side effects:

You must tell your doctor immediately if you notice these serious side effects mentioned. You may need urgent medical treatment.

- Fever with muscle stiffness, sweating or a lowered level of consciousness (a disorder called "Neuroleptic Malignant Syndrome").

Common side effects (seen in more than 1 out of 100 and less than 1 out of 10 patients) are headache, dizziness, sleeplessness, tiredness, fainting, hallucinations, unusual dreams including nightmares, agitation, aggressive behaviour, pain, loss of appetite, digestive disturbances, including diarrhoea, nausea and vomiting, incontinence, muscle cramps, rash, itching, , colds and accidents.

Uncommon side effects (seen in more than 1 out of 1,000 and less than 1 out of 100 patients) are seizures, slow heart rate, bleeding in the digestive system, stomach and duodenal ulcer, and abnormal levels of the substance creatine kinase in the blood.

Rare side effects (seen in more than 1 out of 10,000 and less than 1 out of 1,000 patients) are liver disorders including hepatitis, heart problems like abnormal heart rate, as well as symptoms such as shaking, stiffness or uncontrollable movement of the face and tongue, but also of the limbs.

If hallucinations, agitation, aggressive behaviour, convulsions or brief fainting episodes occur, you should contact your doctor as the dose might need to be lowered or treatment stopped.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ARIPEZ

Keep out of the reach and sight of children.

Do not use Aripez after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Aripez contains

The active substance is donepezil hydrochloride.

5 mg

Each tablet contains 5 mg donepezil hydrochloride, equivalent to 4.56 mg donepezil.

10 mg

Each tablet contains 10 mg donepezil hydrochloride, equivalent to 9.12 mg donepezil.

The other ingredients are: tablet core contains lactose, microcrystalline cellulose, pregelatinised maize starch, hypromellose and magnesium stearate. The film coating contains polyvinyl alcohol, titanium dioxide (E171), macrogol, talc.

In addition the 10 mg tablets contain: iron oxide yellow (E172).

What Aripez looks like and contents of the pack

Aripez 5 mg tablets are white film coated oval shaped tablets, debossed with "93" on one side and "7320" on the other.

Aripez 10 mg tablets are yellow film coated oval shaped tablets, debossed with "93" on one side and "7321" on the other.

The 5 mg tablets are available in pack sizes of 1, 7, 14, 28, 30, 50, 56, 60, 84, 98 and 120 film-coated tablets. Hospital pack: 50 (50 x 1) film-coated tablets. Calendar packs: 28, 56 and 98 film-coated tablets.

The 10 mg tablets are available in pack sizes of 1, 7, 14, 28, 30, 50, 56, 60, 84, 98 and 120 film-coated tablets. Hospital pack: 50 (50 x 1) film-coated tablets. Calendar pack: 28, 56, 98 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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