

PACKAGE LEAFLET: Information for the patient

ALPRO

Film-coated tablets – 10 mg
(Donepezil hydrochloride)

Read this leaflet carefully before you start using the 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 becomes worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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

1. WHAT ALPRO IS AND WHAT IT IS USED FOR

Alpro contains the active substance donepezil hydrochloride, which belongs to a group of medicines called acetylcholinesterase inhibitors.

This drug is used to treat the symptoms of dementia in people diagnosed with mild and moderately severe Alzheimer's disease. Symptoms include increasing memory loss, confusion and behavioural changes. As a result, sufferers of Alzheimer's disease find it more and more difficult to carry out their normal daily activities.

Alpro is for use in adult patients only.

Ask your doctor if you want to know why you have been given this drug.

2. BEFORE YOU TAKE ALPRO

Do not take Alpro:

- if you are allergic (hypersensitive) to donepezil hydrochloride or to any of the excipients of Alpro tablets,
- if you are breastfeeding.

Take special care with ALPRO

Ask your doctor or pharmacist before starting to take Alpro if you have or have had:

- stomach or duodenal ulcers;
- seizures (fits) or convulsions;
- heart disease (irregular or very slow heart beat);
- asthma or other long- term lung disease;
- liver problems or hepatitis;
- difficulty passing urine or mild kidney disease.

Also tell your doctor if you are pregnant or think you might be pregnant.

Children and adolescents

Alpro is not recommended for use in children and adolescents (younger than 18 years of age).

Taking other medicines

Taking other medicines may affect or be affected by Alpro.

Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicine, including those taken without a prescription. Don't forget to inform your doctor if you are given another drug during treatment. Especially tell your doctor if you are taking any of the following types of medicines:

- other Alzheimer disease medicines, e.g. galantamine;
- pain killers or for treatment of arthritis e.g. aspirin, non-steroidal anti-inflammatory drugs (NSAID), such as ibuprofen, or diclofenac sodium;
- anticholinergic medicines, e.g. tolterodine;
- antibiotics, e.g. erythromycin, rifampicin;
- antifungal medicines, e.g. ketoconazole;

- antidepressants, e.g. fluoxetine;
- anticonvulsants, e.g. phenytoin, carbamazepine;
- medication for a heart condition, e.g. quinidine, beta-blockers (propranolol and atenolol);
- muscle relaxants, e.g. diazepam, succinylcholine;
- general anaesthetics;
- medicines obtained without a prescription, e.g. herbal remedies.

If you are going to have an operation that requires you to have a general anaesthetic, you should tell your doctor and anaesthetist that you are taking Alpro. This is because your medicine may affect the amount of anaesthetic needed.

Alpro can be used in patients with kidney disease or mild to moderate liver disease. Tell your doctor first if you have kidney or liver disease. Patients with severe liver disease should not take Alpro.

Taking Alpro with food and drinks

Food will not influence the effect of Alpro tablets.

Alpro should not be taken with alcohol because alcohol may change its effect.

Pregnancy and breast-feeding

If you are pregnant, or think you might be pregnant, ask your doctor for advice before taking any medicine.

Alpro must not be used while breast-feeding.

Driving and using machines

Alzheimer's disease may impair your ability to drive or use machines. Alpro can cause tiredness, dizziness and muscle cramps. If you experience any of these effects, you must not drive or operate machines.

Important information about some of the excipients of Alpro

This medicine contains lactose. If you have been told by your doctor that you have intolerance to some sugars, you should contact your doctor before taking Donepezil.

3. HOW TO TAKE ALPRO

Always take Alpro exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Usually, you will start by taking 5 mg every night. After one month, your doctor may tell you to take 10 mg every night. Swallow your tablet with a glass of water (200 – 250 ml) before you go to bed at night. The dose you will take may change depending on the duration of use of the medicine and on what your doctor recommends. The maximum recommended dose is 10 mg each night before going to bed. Always follow your doctor's or pharmacist's advice about how and when to take your medicine. Do not alter the dose yourself without your doctor's advice.

For how long should you take Alpro?

Your doctor or pharmacist will advise you on how long you should continue to take your tablets. You will need to see your doctor from time to time to review your treatment and assess your symptoms.

If you take more Alpro than you should

DO NOT take more than one tablet each day. Call your doctor immediately if you take more than you should. Or if the children have wrongly taken this medicine, please contact your doctor, or the local hospital or emergency department to get an opinion on the risk and advice on the action to be taken. Always take your tablets and their package with you in the hospital, in order for the doctors to recognize the medicine you have taken. Symptoms of overdose include feeling and being sick, drooling from the mouth, sweating, decreased heart rate, reduction in blood pressure (dizziness during standing), breathing problems, loss of consciousness and convulsions and crises.

If you forget to take Alpro

If you forget to take a tablet, just take the next dose at its usual time. Do not take a double dose (or higher) to make up for a forgotten tablet. If you forget to take your medicine for more than one week, call your doctor before taking any more medicine.

If you stop taking Alpro

Do not stop taking the tablets unless you are told to do so by your doctor. If you stop taking Alpro, the benefits of your treatment will gradually disappear.

4. POSSIBLE SIDE EFFECTS

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

The majority of side effects are dose-related and disappear when the dose is reduced or the treatment discontinued. Some side effects can occur at the beginning of treatment and resolve spontaneously as the treatment continues.

The frequency of possible side effects is shown in the table below:

Very common:	occur in more than 1 in 10 users
Common:	occur in less than 1 in 10, but more than 1 in 100 users
Uncommon:	occur in less than 1 in 100 users but more than 1 in 1,000 users
Rare:	occur in less than 1 in 1,000, but more than 1 in 10,000 users
Very rare:	occur in less than 1 in 10,000 users, including isolated cases

The following side effects have been reported by people taking donepezil.

Tell your doctor if you have any of these effects while you are taking Alpro.

Serious side effects:

You must tell your doctor immediately if you notice these serious side effects mentioned.

You may need urgent medical treatment:

- muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell, have a high temperature or have dark urine; they may be caused by an abnormal muscle breakdown which can be life threatening and lead to kidney problems (a condition called rhabdomyolysis);
- liver damage e.g. hepatitis; the symptoms of hepatitis are feeling or being sick, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine (probably affecting fewer than 1 in 1,000)
- gastric or duodenal ulcers; the symptoms of ulcers are stomach pain and discomfort (indigestion) felt between the navel and the sternum (probably affecting fewer than 1 in 100)

- bleeding in the stomach or intestines; this may cause you to pass black tar-like stools or visible blood from the rectum (probably affecting fewer than 1 in 100)
- seizures (fits) or convulsions (probably affecting fewer than 1 in 100);
- fever with muscle stiffness, sweating or a lowered level of consciousness (a disorder called “Neuroleptic Malignant Syndrome”) (may affect up to 1 in 10,000 people).

Very common side effects (probably affecting more than 1 in 10):

- diarrhoea
- feeling or being sick
- headache.

Common side effects (probably affecting up to 1 in 10):

- muscle cramps
- tiredness
- difficulty in sleeping (insomnia)
- common cold
- loss of appetite
- hallucinations (seeing or hearing things that are not really there)
- unusual dreams including nightmares
- agitation
- aggressive behaviour
- fainting
- dizziness
- stomach feeling uncomfortable
- rash
- itching
- passing urine uncontrollably
- pain
- accidents (patients may be more prone to falls and accidental injury).

Uncommon side effects (probably affecting fewer than 1 in 100):

- slow heart beat;
- salivary hypersecretion

Rare side effects (probably affecting fewer than 1 in 1,000):

- stiffness, shaking or uncontrollable movement especially of the face and tongue but also of the limbs.

You should also tell your doctor if you notice any other side effects not listed in this leaflet while you are taking Alpro.

5. HOW TO STORE ALPRO

Keep out of the reach and sight of children.

Do not use Alpro after the expiry date which is stated on the package.

Store below 25°C.

Store in the original package to protect it from light and humidity.

6. FURTHER INFORMATION

What Alpro film-coated tablets contain

The **active substance** is donepezil hydrochloride.

Each film-coated tablet contains 10 mg donepezil hydrochloride.

The **excipients** are:

tablet core: lactose monohydrate, starch, microcrystalline cellulose, hydroxypropyl cellulose, magnesium stearate, silicified microcrystalline cellulose

film coating: polyvinyl alcohol, titanium dioxide, macrogol, talc.

Contents of the pack

Box with 30 film-coated tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was last revised in November 2023.