Package leaflet: information for the user

Donepezil hydrochloride Ipca 5 mg film-coated tablets
Donepezil hydrochloride Ipca 10 mg film-coated tablets

Donepezil hydrochloride monohydrate

Read the entire leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- Are you experiencing a lot of side effects? Or do you experience a side effect that is not listed in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet

1. What is Donepezil hydrochloride Ipca and what is it used for?

Donepezil hydrochloride Ipca contains a substance called donepezil hydrochloride monohydrate. This medicine belongs to a group of medicines called 'acetylcholinesterase inhibitors'. Donepezil increases the levels of a substance (called acetylcholine) in the brain. This substance plays a role in memory function by ensuring that acetylcholine is broken down more slowly.

It is used to treat the symptoms of dementia in people diagnosed with mild to moderately severe Alzheimer's disease. The symptoms are: increasing memory loss, confusion, and behavioral changes. As a result, people with Alzheimer's disease find it increasingly difficult to carry out their normal daily activities.

This medicine is intended for use by adults only.

2. When should you not take this medicine or be extra careful with it?

When should you not take this medicine?
- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

You are allergic to substances derived from piperidine.

When should you be extra careful with this medicine?
Tell your doctor or pharmacist before you start taking this medicine if you have or have had any of the following conditions:

- ulcers in the stomach or duodenum;
- seizures or convulsions;
- a heart condition (such as irregular or very slow heartbeat, heart failure, heart attack);
- a heart condition called "prolonged QT interval," or a history of certain abnormal heart rhythms called Torsade de Pointes, or if someone in your family has a "prolonged QT interval"
- low levels of magnesium or potassium in your blood
- asthma or another long-term lung disease;
- liver problems or hepatitis;
- difficulty urinating or a mild kidney disease.

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

If you are undergoing surgery that requires you to have a full anesthetic, you must tell your doctor and the anesthetist that you are taking Donepezil Hydrochloride Ipca tablets. This is because your medicine may affect the amount of anesthetic you need.

This medicine can be used in patients with kidney disease or mild to moderate liver disease. Tell your doctor immediately if you have a kidney or liver disease. Patients with severe liver disease should not take Donepezil Hydrochloride Ipca tablets.

Contact your doctor or pharmacist before taking this medicine.

Children and adolescents up to 18 years
This medicine is not recommended for use in children and adolescents up to 18 years.

Are you taking any other medicines?
Are you taking any other medicines besides Donepezil Hydrochloride Ipca tablets, or have you recently taken any, or is there a possibility that you will take other medicines in the near future? If so, tell your doctor or pharmacist. This also applies to medicines not prescribed by your doctor but bought by yourself at the pharmacy or drugstore. It also applies to medicines you may take in the future if you are still taking this medicine. This is because these medicines can enhance or weaken the effects of this medicine.

Especially tell your doctor if you are taking any of the following types of medicines:
- medicines for heart rhythm disorders (e.g., amiodarone, sotalol, and quinidine);
- medicines for depression (e.g., citalopram, escitalopram, amitriptyline), medicines for psychoses (e.g., pimozide, sertindole, ziprasidone), medicines for bacterial infections (such as clarithromycin, erythromycin, levofloxacin, moxifloxacin).
- other medicines for Alzheimer's disease, such as galantamine;
- painkillers or treatment for arthritis, such as aspirin, NSAIDs (non-steroidal anti-inflammatory drugs) like ibuprofen or sodium diclofenac;
- anticholinergic medicines, such as tolterodine;
- antibiotics, such as erythromycin, rifampicin;
- antifungal medicines, such as ketoconazole, itraconazole;
- antidepressants, such as fluoxetine;
- antiepileptics, such as phenytoin, carbamazepine;
- medicines for a heart condition, such as quinidine, beta-blockers (propranolol and atenolol);
- muscle relaxants, such as diazepam, succinylcholine;

- medicines available without a prescription, such as herbal medicines.

If you are undergoing surgery that requires you to receive a full anesthetic, you must tell your doctor and the anesthetist that you are taking this medicine. This is because your medicine can affect the amount of anesthetic you need.

Tell your doctor or pharmacist the name of your healthcare provider. Your healthcare provider will help you take your medicine as prescribed.

What should you pay attention to with food, drink, and alcohol?
Food does not affect the effect of this medicine.
This medicine should not be taken with alcohol, as alcohol can affect the effect of the tablets.

Pregnancy and breastfeeding
This medicine should not be used during the period of breastfeeding. Are you pregnant, do you think you might be pregnant, or do you want to become pregnant? Then contact your doctor or pharmacist before using this medicine.

Driving and using machines
Due to Alzheimer's disease, you may have impaired driving ability or a reduced ability to operate machines. You should not perform these activities unless your doctor tells you that you can do so safely.
Your medicine can also cause fatigue, dizziness, and muscle cramps. If you experience any of these side effects, you should not drive vehicles or operate machines.

Donepezil hydrochloride Ipca contains lactose
If your doctor has told you that you do not tolerate certain sugars, contact your doctor before taking this medicine.

3. How to take this medicine?

- Always take this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.
- You usually start by taking 5 mg every evening. After one month, your doctor may tell you to take 10 mg every evening.
- Swallow your tablet in the evening, before going to bed, with a few sips of water.
- The strength of the tablets you take may change depending on how long you have been taking the medicine and your doctor's recommendations. The maximum recommended dosage is 10 mg every evening.
- Always follow your doctor or pharmacist's advice on how and when to take your medicine.
- Never change the dosage yourself without your doctor's advice.
- If you have liver problems, your doctor may need to adjust the dose to your needs (see section 2 'When to be extra careful with this medicine?').

Use in children and adolescents under 18 years
This medicine is not intended for use in children and adolescents under 18 years.

Have you taken too much of this medicine?

Do not take more than one tablet per day. Contact your doctor immediately if you have taken too much of this medicine. If you cannot contact your doctor, contact the Emergency Department of the local hospital directly. Always take the tablets and the box with you to the hospital so that the doctor knows what you have taken.

Symptoms of overdose include: nausea, vomiting, drooling, sweating, low heart rate, low blood pressure (feeling lightheaded or dizzy when standing), loss of consciousness, and seizures or convulsions, severe nausea, vomiting, salivation (drooling), slow heart rate (bradycardia), breathing problems (respiratory depression), muscle weakness (collapse), and involuntary muscle contractions (convulsions). Increasing muscle weakness may occur, potentially leading to a life-threatening condition if respiratory muscles are involved.

Have you forgotten to take this medicine?
If you have forgotten to take a tablet, just take one tablet the next day at the usual time. Do not take a double dose to make up for a forgotten dose. If you have forgotten to take your medicine for more than a week, contact your doctor before taking the medicine again.

If you stop taking this medicine
Do not stop taking your medicine unless your doctor tells you to do so. If you stop taking this medicine, the beneficial effects of your treatment will gradually disappear.

How long should you continue taking this medicine?
Your doctor will advise you on how long to continue taking this medicine. You should visit your doctor regularly to discuss your treatment and have your symptoms assessed.

Do you have any other questions about using this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them.

The following side effects have been reported by people taking this medicine.

Tell your doctor if you experience any of these side effects while taking this medicine.

Serious side effects:

Contact your doctor immediately if you notice any of the above serious side effects. You may need urgent medical attention.

- liver damage, for example, hepatitis. Symptoms of hepatitis include: nausea, vomiting, loss of appetite, a general feeling of discomfort, fever, itching, yellowing of the skin and eyes, and dark-colored urine (occurs in less than 1 in 1000 people).
- ulcers in the stomach or duodenum. Symptoms of ulcers include: stomach pain and indigestion between the navel and the breastbone (occurs in less than 1 in 100 people).
- bleeding in the stomach or intestines. This can result in black, tarry stools or visible blood from the rectum (occurs in less than 1 in 100 people).
- seizures or convulsions (occurs in less than 1 in 100 people).

- fever with muscle stiffness, sweating or a reduced level of consciousness (a condition called "Neuroleptic Malignant Syndrome") (occurs in less than 1 in 10,000 people).

Muscle weakness, tenderness or pain and especially if you feel unwell at the same time, have a high temperature or dark-colored urine. These side effects may be due to abnormal muscle breakdown which can be life-threatening and lead to kidney problems (a condition called rhabdomyolysis).
In addition to the serious side effects mentioned above, the following side effects have also been reported:

Very common side effects (occur in more than 1 in 10 people):
- diarrhea;
- nausea, vomiting (nausea);
- headache.

Common side effects (occur in less than 1 in 10 people):
- muscle cramp;
- fatigue;
- sleep problems (insomnia);
- cold;
- decreased appetite;
- hallucinations (seeing or hearing things that are not really there);
- unusual dreams, including nightmares;
- agitation;
- aggressive behavior;
- fainting;
- dizziness;
- uncomfortable feeling in the stomach;
- skin rash;
- itching;
- uncontrolled loss of urine;
- pain;
- accidents (patients may fall more easily and accidentally injure themselves).

Sometimes occurring side effects (occur in less than 1 in 100 people):
- slow heartbeat.

Rare side effects (occur in less than 1 in 1000 people):
stiffness, trembling or uncontrolled movement, especially of the face and tongue, but also of the limbs.
Frequency not known:
- Changes in heart activity that can be observed on an electrocardiogram (ECG) and are called “prolonged QT interval”.
- Rapid, irregular heartbeat, fainting; these may be symptoms of a life-threatening condition called Torsade de Pointes.

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet.

5. How to store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. It can be found on the box. It includes a month and a year. The last day of that month is the expiry date.

There are no special storage conditions for this medicine.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?

- The active substance(s) in this medicine is (are) donepezil hydrochloride monohydrate.

Each 5 mg tablet contains 5 mg donepezil hydrochloride monohydrate and each 10 mg tablet contains 10 mg donepezil hydrochloride monohydrate.

- The other substance(s) in this medicine is (are):

Tablet core: microcrystalline cellulose, dried maize starch, hydroxypropyl cellulose, and sodium stearyl fumarate.
Coating: HPMC/hypromellose, titanium dioxide (E171), purified talc, and polyethylene glycol (6000).
Additionally, the 10 mg tablet contains yellow iron(III) oxide (E172).

What do Donepezil hydrochloride Ipca film-coated tablets look like and what is in a package?
There are two strengths of Donepezil hydrochloride Ipca film-coated tablets, 5 mg and 10 mg.

Donepezil hydrochloride Ipca 5 mg film-coated tablets are white to off-white, round, biconvex, film-coated tablets, with the marking “C” on one side and “7” on the other side.

Donepezil hydrochloride Ipca 10 mg film-coated tablets are yellow, round, biconvex, film-coated tablets, with the marking “C” on one side and “6” on the other side.

Donepezil hydrochloride Ipca film-coated tablets are available in blister packs of 28, 50, 56, and 98 tablets.

Not all pack sizes may be marketed.

Marketing authorization holder and manufacturer

Ipca Produtos Farmaceuticos Unipessoal Lda
Rua Jose Nogueria Vaz, Lote 104-Lj Esq 2625-099 Povoa de Santa Iria Portugal

Manufacturer PharmaS d.o.o.
Industrijska cesta 5
44317 Potok, Popovača, Croatia

Registered under:
Donepezil hydrochloride Ipca 5 mg film-coated tablets, RVG 111596

Donepezil hydrochloride Ipca 10 mg film-coated tablets, RVG 111597
This medicine is registered in EEA member states under the following names:

Netherlands	Donepezil hydrochloride Ipca 5mg film-coated tablets Donepezil hydrochloride Ipca 10mg film-coated tablets
Spain	Uxazen 5mg film-coated tablets EFGUxazen 10mg film-coated tablets EFG

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