

Package leaflet: Information for the user

Donepezil Hydrochloride Bluefish 5 mg film-coated tablets **Donepezil Hydrochloride Bluefish 10 mg film-coated tablets** donepezil hydrochloride

Read all of this 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.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Donepezil Hydrochloride Bluefish is and what it is used for
2. What you need to know before you take Donepezil Hydrochloride Bluefish
3. How to take Donepezil Hydrochloride Bluefish
4. Possible side effects
5. How to store Donepezil Hydrochloride Bluefish
6. Contents of the pack and other information

1. What Donepezil Hydrochloride Bluefish is and what it is used for

Donepezil Hydrochloride Bluefish contains the active substance donepezil hydrochloride. Donepezil Hydrochloride Bluefish belongs to a group of medicines called acetylcholinesterase inhibitors. Donepezil hydrochloride increases the levels of a substance (acetylcholine) in the brain involved in memory function by slowing down the breakdown of acetylcholine.

It is used to treat the symptoms of dementia in people diagnosed as having mild and moderately severe Alzheimer's disease. The 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.

Donepezil Hydrochloride Bluefish is for use in adult patients only.

2. What you need to know before you take Donepezil Hydrochloride Bluefish

Do not take Donepezil Hydrochloride Bluefish

- if you are allergic (hypersensitive) to donepezil hydrochloride, or to piperidine derivatives, or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking **Donepezil** Hydrochloride Bluefish if you have or have had:

- stomach or duodenal ulcers
- seizures (fits) or convulsions
- a heart condition (such as irregular or very slow heart beat, heart failure, myocardial infarction)
- a heart condition called 'prolonged QT interval' or a history of certain abnormal heart rhythms called Torsade de Pointes or if anyone in your family have 'prolonged QT interval'
- low levels of magnesium or potassium in your blood

- 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

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

Other medicines and Donepezil Hydrochloride Bluefish

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine. This includes medicines that your doctor has not prescribed for you but which you have bought yourself from a chemist/pharmacist. It also applies to medicines you may take some time in the future if you continue to take Donepezil Hydrochloride Bluefish. This is because these medicines may weaken or strengthen the effects of Donepezil Hydrochloride Bluefish.

In particular it is important to tell your doctor if you are taking any of the following types of medicines:

- medicines for heart rhythm problems e.g. amiodarone, sotalol,
- medicines for depression e.g. citalopram, escitalopram, amitriptyline, fluoxetine
- medicines for psychosis e.g. pimozide, sertindole, ziprasidone
- medicines for bacterial infections e.g. clarithromycin, erythromycin, levofloxacin, moxifloxacin, rifampicin
- anti-fungal medicines e.g. ketoconazole
- other Alzheimer's disease medicines, e.g. galantamine
- pain killers or treatment for arthritis e.g. aspirin, non-steroidal anti-inflammatory (NSAID) drugs such as ibuprofen, or diclofenac sodium
- anticholinergics medicines, e.g. tolterodine
- 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 anaesthetic
- 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 the anaesthetist that you are taking Donepezil Hydrochloride Bluefish. This is because your medicine may affect the amount of anaesthetic needed.

Donepezil Hydrochloride Bluefish 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 Donepezil Hydrochloride Bluefish.

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

Donepezil Hydrochloride Bluefish with food and drink and alcohol

Food will not influence the effect of Donepezil Hydrochloride Bluefish.

Donepezil Hydrochloride Bluefish should not be taken with alcohol because alcohol may change its effect.

Pregnancy and breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Donepezil Hydrochloride Bluefish should not be used during pregnancy unless clearly necessary.

Donepezil Hydrochloride Bluefish should not be used while breast-feeding.

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. If you experience any of these effects you must not drive or operate machinery.

Donepezil Hydrochloride Bluefish 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 Hydrochloride Bluefish.

3. How to take Donepezil Hydrochloride Bluefish

How much Donepezil Hydrochloride Bluefish should you take

Always take this medicine exactly as your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

Initially, the recommended dose is 5 mg (one white tablet) every night before you go to bed. After one month, your doctor may tell you to take 10 mg (one yellow tablet) every night before you go to bed.

If you experience abnormal dreams, nightmares or difficulty in sleeping (see section 4) your doctor may advise you to take Donepezil Bluefish in the morning.

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 recommends. The maximum recommended dose is 10 mg each night.

Always follow your doctor or pharmacist's advice about how and when to take your medicine. Do not alter the dose yourself without your doctor's advice.

How to take your medicine

Swallow your Donepezil Hydrochloride Bluefish with a drink of water before you go to bed at night.

Use in Children and adolescents

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

For how long should you take Donepezil Hydrochloride Bluefish?

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 Donepezil Hydrochloride Bluefish than you should

Do not take more than one tablet each day. Call your doctor or the nearest hospital emergency department immediately if you take more of the medicine than you should. Always take the remaining tablets and this leaflet with you to the hospital so that the doctor knows what has been taken.

Symptoms of overdosing may include nausea (feeling and being sick) and vomiting (being sick), drooling, sweating, slow heart rate, low blood pressure (light-headedness or dizziness when standing), breathing problems, losing consciousness and seizures (fits) or convulsions.

If you forget to take Donepezil Hydrochloride Bluefish

If you forget to take a tablet, just take one tablet the following day at the usual time. Do not take a double dose 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 Donepezil Hydrochloride Bluefish

Do not stop taking the tablets unless told to do so by your doctor. If you stop taking Donepezil Tablets, the benefits of your treatment will gradually fade away.

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

4. Possible side effects

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

The following side effects have been reported by people taking Donepezil Hydrochloride Bluefish.

Tell your doctor if you have any of these effects while you are taking Donepezil Hydrochloride Bluefish.

Serious side effects:

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

- stomach or duodenal ulcers. The symptoms of ulcers are stomach pain and discomfort (indigestion) felt between the navel and the breast bone (may affect up to 1 in 100 people).
- bleeding in the stomach or intestines. This may cause you to pass black tar like stools or visible blood from the rectum (may affect up to 1 in 100 people).
- seizures (fits) or convulsions (may affect up to 1 in 100 people)
- liver damage e.g. hepatitis. The symptoms of hepatitis are nausea (feeling sick), or vomiting (being sick), loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine (may affect up to 1 in 1,000 people).
- Tell a physician immediately if you notice fever with muscle stiffness, sweating or a lowered level of consciousness (a disorder known as "Neuroleptic Malignant Syndrome"), (may affect up to 1 in 10,000 people).
- 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) (may affect up to 1 in 10,000 people).
- fast, irregular heart beat and fainting, which could be symptoms of a life-threatening condition known as Torsade de Pointes (frequency cannot be estimated from the available data)

Other possible side effects:

Very common side effects: may affect more than 1 in 10 people

- diarrhoea
- feeling or being sick
- headaches

Common side effects: may affect up to 1 in 10 people

- muscle cramp
- tiredness
- difficulty in sleeping (insomnia)
- the 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: may affect up to 1 in 100 people

- slow heart beat
- salivary hypersecretion

Rare side effects: may affect up to 1 in 1,000 people

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

Not known: cannot be estimated from the available data

- Changes in the heart activity which can be seen on an electro-cardiogram (ECG) called 'prolonged QT interval'
- Libido increased, hypersexuality
- Pisa syndrome (a condition involving involuntary muscle contraction with abnormal bending of the body and head to one side)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Donepezil Hydrochloride Bluefish

- Keep this medicine out of the sight and reach of children.
 - Do not use this medicine after the expiry date which is stated on the Carton and blister after EXP. The expiry date refers to the last day of that month.
- This medicinal does not require any special storage conditions.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of/ throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Donepezil Hydrochloride Bluefish contains

The active substance is Donepezil hydrochloride.

Each Donepezil Hydrochloride 5 mg tablet contains donepezil hydrochloride monohydrate equivalent to donepezil hydrochloride 5 mg.

Each Donepezil Hydrochloride 10 mg tablet contains donepezil hydrochloride monohydrate equivalent to donepezil hydrochloride 10 mg.

The other ingredients are:

Core: Lactose monohydrate, maize starch, cellulose microcrystalline, low-substituted hydroxypropyl cellulose, magnesium stearate

Coating:

For 5 mg: Hypromellose (E464), titanium dioxide (E171), macrogol, talc (E553b)

For 10 mg: Hypromellose (E464), titanium dioxide (E171), macrogol, talc (E553b), iron oxide yellow (E172)

What Donepezil Hydrochloride Bluefish looks like and contents of the pack

Donepezil Hydrochloride Bluefish is presented as 5 mg, and 10 mg tablets. The tablets are described below.

5 mg: White to off-white, round, bevelled edge, biconvex, approximately 7.14 mm in diameter film coated tablets with inscription "5" on one side and plain on other side.

10 mg: Yellow, round, biconvex, approximately 8.73 mm in diameter film coated tablets with inscription "10" on one side and plain on other side.

Donepezil Hydrochloride Bluefish 5 mg / 10 mg are available in the following pack sizes:

PVC/Alu Blister in outer carton:

For 5 mg: 7, 28, 56, 98, 119, 120 tablets

For 10 mg: 28, 56, 98, 119, 120 tablets

HDPE Bottle: 100 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder

Bluefish Pharmaceuticals AB

P.O. Box 490 13,

100 28 Stockholm

Sweden

Manufacturer

Bluefish Pharmaceuticals AB

Gävlegatan 22

113 30 Stockholm

Sweden

This medicinal product is authorized in the Member States of the EEA under the following names:

Austria	Donepezil Bluefish 5 mg Filmtabletten Donepezil Bluefish 10 mg Filmtabletten
Germany	Donepezilhydrochlorid Bluefish 5 mg Filmtabletten Donepezilhydrochlorid Bluefish 10 mg Filmtabletten Donepezilo Bluefish 5 mg comprimidos recubiertos con película EFG
Spain	Donepezilo Bluefish 10 mg comprimidos recubiertos con película EFG
Portugal	Donepezil Bluefish 5 mg Comprimidos revestidos por película Donepezil Bluefish 10 mg Comprimidos revestidos por película
Ireland	Donepezil Hydrochloride Bluefish 5 mg film-coated Tablets Donepezil Hydrochloride Bluefish 10mg film-coated Tablets
Poland	Donepezil Bluefish

This leaflet was last revised in: