

PACKAGE LEAFLET

Package leaflet: Information for the user

Fexofenadine Bluefish 180mg film-coated tablets

Fexofenadine 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 Fexofenadine Bluefish is and what it is used for
2. What you need to know before you take Fexofenadine Bluefish
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1. What Fexofenadine Bluefish is and what it is used for

Fexofenadine Bluefish contains fexofenadine hydrochloride, which is a non-drowsy antihistamine.

Fexofenadine Bluefish 180 mg is used in adults and adolescents of 12 years and older to relieve the symptoms that occur with long term allergic skin reactions (chronic idiopathic urticaria) such as itching, swelling and rashes.

2. What you need to know before you take Fexofenadine Bluefish

Do not take Fexofenadine Bluefish

- if you are allergic to fexofenadine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Fexofenadine Bluefish if :

- you have or ever had heart disease, since this kind of medicine may lead to a fast or irregular heart beat
- you are elderly
- you have problems with your liver or kidneys.

If any of these apply to you, or if you are not sure, tell your doctor before taking Fexofenadine Bluefish.

Other medicines and Fexofenadine Bluefish

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you are taking apalutamide (a medicine to treat prostate cancer), as the effect of fexofenadine may be decreased.

Indigestion remedies containing aluminium and magnesium may affect the action of Fexofenadine Bluefish by lowering the amount of medicinal product absorbed. It is recommended that you leave about 2 hours between the time that you take Fexofenadine Bluefish and your indigestion remedy.

Pregnancy and breast-feeding

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.

Fexofenadine Bluefish should not be used during pregnancy unless clearly necessary.

Fexofenadine Bluefish is not recommended during breast-feeding.

Driving and using machines

Fexofenadine Bluefish is unlikely to affect your ability to drive or operate machinery. However, you should check that these tablets do not make you feel sleepy or dizzy before driving or operating machinery.

Fexofenadine Bluefish contains less than 1 mmol sodium (23 mg) per 180mg tablet, that is to say essentially 'sodium-free'.

3. How to take Fexofenadine Bluefish

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

For adults and children aged 12 years and over

The recommended dose is one tablet (180 mg) daily.

Take your tablet with water before a meal.

This medicine starts to relieve your symptoms within 1 hour and lasts for 24 hours.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

If you take more Fexofenadine Bluefish than you should

If you take too many tablets, contact your doctor or the nearest hospital emergency department immediately. Symptoms of an overdose in adults are dizziness, drowsiness, fatigue and dry mouth.

If you forget to take Fexofenadine Bluefish

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

Take the next dose at the usual time as prescribed by your doctor.

If you stop taking Fexofenadine Bluefish

Tell your doctor if you want to stop taking Fexofenadine Bluefish before you have finished your course of treatment.

If you stop taking Fexofenadine Bluefish earlier than planned, your symptoms may return.

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

4. Possible side effects

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

Tell your doctor immediately and stop taking Fexofenadine Bluefish if you experience:

- swelling of the face, lips, tongue or throat and difficulty breathing, as these may be signs of a serious allergic reaction.

The following undesirable effects have been reported in clinical trials, with an incidence similar to those observed in patient who did not receive the drug(placebo)

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

- headache
- drowsiness
- feeling sick (nausea)
- dizziness

Uncommon side effects (may affect up to 1 in 100 people):

- tiredness
- sleepiness

Additional side effects (frequency not known: cannot be estimated from the available data) which may occur are:

- difficulty sleeping (insomnia)
- sleeping disorders
- bad dreams
- nervousness
- blurred vision
- fast or irregular heart beat
- diarrhoea
- skin rash and itching
- hives
- serious allergic reactions which can cause swelling of the face, lips, tongue or throat, flushing, chest tightness, and difficulty breathing.

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 [the national reporting system listed in Appendix V](#).* By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fexofenadine Bluefish

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the package after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Fexofenadine Bluefish contains

- The active substance is fexofenadine hydrochloride. Each tablet contains 180 mg of fexofenadine hydrochloride.
- The other ingredients are microcrystalline cellulose, maize starch, croscarmellose sodium, povidone, magnesium stearate, hypromellose, titanium dioxide (E171), macrogol, yellow iron oxide (E172).

What Fexofenadine Bluefish looks like and contents of the pack

Fexofenadine Bluefish 180 mg, film-coated tablets are Yellow, 17 mm x 8 mm capsule-shaped, biconvex, film-coated tablet with a score line on one side.

PVC/PVdC/Al blisters, packaged into cardboard boxes. 7, 10, 15, 20, 30, 50, 100 and 200 (10x20) tablets per package.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

<[To be completed nationally]>

Manufacturer

Bluefish Pharmaceuticals AB
Gävlegatan 22
113 30 Stockholm
Sweden

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

Sweden	Fexofenadine Bluefish 180 mg filmdragerade tabletter
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This leaflet was last revised in 2023-03-28