

Package leaflet: Information for the user

Hydroxyzine Bluefish AB 10 mg film-coated tablets **Hydroxyzine Bluefish AB 25 mg film-coated tablets** hydroxyzine hydrochloride

Read all of this leaflet carefully before you start using 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.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Hydroxyzine Bluefish AB is and what it is used for
2. What you need to know before you use Hydroxyzine Bluefish AB
3. How to use Hydroxyzine Bluefish AB
4. Possible side effects
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6. Contents of the pack and other information

1. What Hydroxyzine Bluefish AB is and what it is used for

Hydroxyzine Bluefish AB belongs to a group of medicines called sedating antihistamines. It suppresses certain functions in the brain without creating a habit. It also blocks histamine, a substance found in body tissues. It is effective against anxiety and itching.

Hydroxyzine Bluefish AB is used to treat

- anxiety in adults
- itching (pruritus) in adults, adolescents and children aged 6 years and above

2. What you need to know before you take Hydroxyzine Bluefish AB

Do not take Hydroxyzine Bluefish AB

- if you are allergic to hydroxyzine hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic (hypersensitive) to cetirizine, aminophylline, ethylenediamine or piperazine derivatives (closely related active substances of other medicines).
- if you have porphyria (a metabolic disease).
- if you are pregnant or breast-feeding (see section “Pregnancy, breast-feeding and fertility” below).
- if your ECG (electrocardiogram) shows a heart rhythm problem called “QT interval prolongation”.
- if you have or had a cardiovascular disease or if your heart rate is very low.
- if you have low salt levels in your body (e.g. low level of potassium or of magnesium).
- if you are taking certain medicines for heart rhythm problems or medicines that may affect the heart rhythm (see “Other medicines and Hydroxyzine Bluefish AB”).
- if anyone in your close family has died suddenly of heart problems.

Warnings and precautions

Talk to your doctor or pharmacist before taking Hydroxyzine Bluefish AB:

- if you have kidney or liver disease or if you are elderly. You might need a lower dose.
- if you have an increased risk of getting fits (seizures)
- if you have any risk factors for stroke.
- if you have an increase in pressure in the eye (glaucoma)
- if you have problems to urinate
- if you have constipation (slow intestinal function).
- if you have a severe muscle weakness (myasthenia gravis).
- if you have mental disorders (dementia).

Hydroxyzine Bluefish AB may be associated with an increased risk of heart rhythm disorder which may be life threatening. Therefore, tell your doctor if you have any heart problems or are taking any other medicines, including medicines obtained without prescription.

While taking Hydroxyzine Bluefish AB, seek immediate medical attention if you experience heart problems such as palpitations, trouble breathing, loss of consciousness. Treatment with hydroxyzine should be stopped.

Dry mouth can be a side effect with Hydroxyzine Bluefish AB use. It is therefore important that you have good oral hygiene during treatment with Hydroxyzine Bluefish AB.

If you are undergoing allergy testing, treatment with Hydroxyzine Bluefish AB should be discontinued at least 5 days before testing. Ask your doctor for advice.

Caution is required in elderly patients. The duration of the treatment should be as short as possible.

Children

Hydroxyzine Bluefish AB is not recommended in children under the age of 6 years as they may have difficulty swallowing tablets.

This medicine should not be used by children under 12 months of age because it has not been studied in this age group.

Younger children are more susceptible to side effects in relation to the central nervous system such as seizures.

Other medicines and Hydroxyzine Bluefish AB

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes any medicines obtained without prescription. Hydroxyzine Bluefish AB can effect or be effected by other medicinal products.

Do not take Hydroxyzine Bluefish AB if you are taking medicine to treat:

- bacterial infections (e.g. antibiotics such as erythromycin, moxifloxacin, levofloxacin).
- fungal infections (e.g. pentamidine).
- heart problems or high blood pressure (e.g., amiodarone, quinidine, disopyramide, sotalol).
- psychoses (e.g. haloperidol).
- depression (e.g. citalopram, escitalopram).
- gastro-intestinal disorders (e.g. prucalopride).
- allergy.
- malaria (e.g. mefloquine, hydroxychloroquine).
- cancer (e.g. toremifene, vandetanib).
- drug abuse or severe pain (methadone).

Also, tell your doctor if you are taking:

- betahistine used to treat Meniere's disease (problems with balance and hearing).

- phenytoin used for the treatment of fits (seizures).
- adrenaline used to treat severe allergic reactions.
- medicines used to treat anxiety or help you sleep.
- anticholinergic medicines for the treatment of e.g. irritable bowel syndrome (digestive disorders) and asthma.
- cimetidine used for the treatment of stomach problems. This may increase the level of Hydroxyzine Bluefish AB in your blood.
- monoamine oxidase inhibitors used for the treatment of depression and Parkinson's disease.
- thiazide diuretics (used to treat e.g. high blood pressure). They may increase the risk for irregular heart rate.

Hydroxyzine Bluefish AB with food, drink and alcohol

Taking Hydroxyzine Bluefish AB at the same time with alcohol should be avoided, because the combination may enhance the effects of Hydroxyzine Bluefish AB and thereby the risk of side effects.

Pregnancy and breast-feeding

Pregnancy

Do not take Hydroxyzine Bluefish AB if you are pregnant or think you may be pregnant. Talk to your doctor if you are planning to have a baby.

Hydroxyzine, the active substance in Hydroxyzine Bluefish AB, passes into the foetus. There is a risk that the foetus may be affected.

The following symptoms may occur in newborn babies of mothers that have used Hydroxyzine Bluefish AB during late pregnancy and/or labour; they were observed immediately or only a few hours after birth: shaking, muscle stiffness and/or weakness, breathing problems and urinary retention (withholding/retaining urine).

Breast-feeding

Do not take Hydroxyzine Bluefish AB if you are breast-feeding.

Stop breast-feeding if treatment with Hydroxyzine Bluefish AB is necessary. Ask your doctor for advice. Hydroxyzine passes into breast milk.

Driving and using machines

Hydroxyzine Bluefish AB may impair your ability to drive or operate machinery, and may cause drowsiness, reduce your attention or decrease your ability to react. Do not drive or operate machinery if you experience any of these effects.

Hydroxyzine Bluefish AB contains lactose

Hydroxyzine Bluefish AB tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Hydroxyzine film-coated tablets contain sodium

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

3. How to take Hydroxyzine Bluefish AB

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

The dose is decided by the doctor, who adjust it individually to you.

Hydroxyzine Bluefish AB should be used at the lowest effective dose and the treatment period should be as short as possible.

25 mg tablet can be divided into two equal doses .
The recommended dose is:

Itching

Adults:

Starting dose is 25 mg in the evening, about an hour before bedtime. Up to 25 mg in total 3-4 times per day can be taken if needed. In adults the maximum daily dose is 100 mg per day.

Children aged 6 years and above:

1-2 mg/kg/day divided into several doses.

In children over 40 kg in weight, the maximum daily dose is 100 mg per day.

In children up to 40 kg, the maximum daily dose is 2 mg/kg/day.

Anxiety

Adults:

–50 mg daily, divided into 3 doses: half a tablet (12.5 mg), half a tablet (12.5 mg) and 1 tablet (25 mg)

In more severe cases, doses up to 100 mg/day can be used. The maximum daily dose for adults is 100 mg per day.

In the treatment of anxiety, drug therapy should only be used to support other forms of treatment. Do not change the dose without talking to your doctor first.

Elderly patients

In the elderly, it is advised to start with half the recommended dose due to the prolonged action. The maximum daily dose in elderly is 50 mg per day.

Patients with kidney problems:

Dosage should be reduced in patients with moderate or severe kidney problems.

Patients with liver problems

In patients with reduced liver activity, it is recommended to reduce the daily dose.

Use in children and adolescents

Hydroxyzine Bluefish AB is only for the treatment of itching in adolescents and children aged 6 years and older.

If your child has difficulty swallowing the tablets, other medicinal products containing hydroxyzine may be more appropriate. Talk to your doctor.

Method of administration

The tablets should be swallowed with a sufficient amount of water. The tablets can be taken with or without food.

If you take more Hydroxyzine Bluefish AB than you should

If you have taken too much Hydroxyzine Bluefish AB, immediately contact your doctor, in particular if a child has taken too much. In the event of overdose, symptomatic treatment could be implemented. An ECG monitoring could be undertaken, because of the possibility of a heart rhythm problem such as QT interval prolongation or Torsade de Pointes.

If you forget to use Hydroxyzine Bluefish AB

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

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

4. Possible side effects

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

Stop taking this medicine and seek immediate medical attention if you experience

- any problems with the heart rhythm such as palpitations, trouble breathing or loss of consciousness. (frequency not known, cannot be estimated from the available data)
- swelling of face, lips, tongue and/or throat, sometimes with difficulties in breathing or swallowing (angioedema) (Very rare side effects that may affect up to 1 in 10,000 people)
- widespread rashes with blisters (acute generalised exanthematous pustulosis), ring-shaped, red and often blistering rashes – common on hands and feet (erythema multiforme), mucosal and skin inflammation in combination with high fever (Stevens-Johnson syndrome) (Very rare side effects that may affect up to 1 in 10,000 people)
- heavy shelling and rejection of the skin (toxic epidermal necrolysis) (frequency not known, cannot be estimated from the available data).

Other side effects that may occur:

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

- sleepiness.

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

- headache,
- drowsiness,
- dry mouth,
- tiredness.

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

- agitation,
- confusion,
- dizziness,
- sleeplessness,
- tremors,
- feeling sick (nausea),
- feeling unwell
- fever.

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

- allergic (hypersensitivity) reactions,
- disorientation, hallucinations (seeing things that are not there),
- fits (seizures), movement disorder (dyskinesia),
- accommodation disturbances of the eye (hard to focus), blurred vision,
- low blood pressure,
- constipation,
- vomiting,
- changes in liver enzyme values (can be seen in blood tests),
- itching, skin rash with redness, spots or blemishes, hives, skin inflammation,
- problems to urinate
- cardiac arrest, effects on the heart rhythm, irregular heart rhythm

Very rare side effects (may affect up to 1 in 10,000 people):

- anaphylactic shock (serious allergic reaction),
- constrictions in the respiratory passage (bronchospasm),
- increased sweating,

Not known (frequency cannot be estimated from the available data):

- reduced number of platelets (thrombocytopenia),
- aggression,
- depression,
- recurring involuntary muscle contractions (tics),
- abnormal prolonged muscle contractions (dystonia),
- sensation of tickling, tingling or numbness (paraesthesia),
- uncontrolled circular movement of the eyes (oculogyration),
- diarrhoea,
- inflammation of the liver,
- bedwetting or difficulty urinating (abnormal urinary excretion),
- extreme weakness (asthenia),
- swelling of tissue due to water retention (oedema),
- weight increased,
- fainting,
- blisters on the arms, legs, abdomen and mucous membranes (pemphigoid).

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 Hydroxyzine Bluefish AB

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

Blister:

This medicinal product does not require any special temperature storage conditions.

HDPE bottle:

This medicinal product does not require any special temperature storage conditions.

Keep the bottle tightly closed in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the carton, blister and bottle 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 Hydroxyzine Bluefish AB contains

- The active substance is hydroxyzine hydrochloride.
- *10 mg tablets*: Each film-coated tablet contains 10 mg hydroxyzine hydrochloride.
- *25 mg tablets*: Each film-coated tablet contains 25 mg hydroxyzine hydrochloride.
- The other ingredients are cellulose microcrystalline, lactose monohydrate, croscarmellose sodium, colloidal anhydrous silica, talc, magnesium stearate, hypromellose 5cPs, macrogol 400, titanium dioxide (E171)

What Hydroxyzine Bluefish AB looks like and contents of the pack

10 mg tablets: White to off-white, 5.0 mm round shaped, biconvex, film coated tablets.

25 mg tablets: White to off-white, 10.0 mm x 4.0 mm caplet shaped, biconvex, film coated tablets with score line on both sides. The tablet can be divided into two equal doses.

10 mg tablets:

Blister:

10, 20, 25, 30, 50, 60, 84, 90, 100 and 250 tablets.

Bottle with child resistant cap:

25, 30, 84 and 100 tablets. Also contains a silica gel desiccant.

Bottle with cap:

250 tablets. Also contains a silica gel desiccant.

This pack is for dose-dispensing.

25 mg tablets:

Blister:

10, 20, 25, 28, 30, 50, 60, 90, 100 and 250 tablets.

Bottle with child resistant cap:

20, 25, 28, 30, 50, 60 and 100 tablets. Also contains a silica gel desiccant.

Bottle with cap:

250 tablets. Also contains a silica gel desiccant.

This pack is for dose-dispensing.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

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

Member state	Proposed (invented) names
Austria	Hydroxyzin Bluefish 10 mg/25 mg Filmdabletten
Poland	Hydroxyzinum Bluefish
Sweden	Hydroxyzine Bluefish AB

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