

## **Package leaflet: Information for the user**

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

#### **1. What Hydroxyzine Bluefish is and what it is used for**

Hydroxyzine Bluefish blocks histamine, a substance found in body tissues. It is effective against anxiety, itching and urticaria.

Hydroxyzine Bluefish is used to treat

- anxiety in adults
- itching (pruritus) associated with hives (urticaria) in adults adolescents and children of 5 years and above

#### **2. What you need to know before you take Hydroxyzine Bluefish**

##### **Do not take Hydroxyzine Bluefish**

- 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”).
- 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:

- 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 heart disease.
- if you have an increase in pressure in the eye (glaucoma)
- if you have problems to urinate
- if you have an imbalance of salts in the body.
- if you have low blood levels of potassium or magnesium.
- if you have constipation (slow intestinal function).
- if you have a severe muscle weakness (myasthenia gravis).
- if you have mental disorders (dementia).

Hydroxyzine Bluefish 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, 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 use. It is therefore important that you have good oral hygiene during treatment with Hydroxyzine Bluefish.

If you are undergoing allergy testing, treatment with Hydroxyzine Bluefish 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 should not be used in children under the age of 5 years.

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

### **Other medicines and Hydroxyzine Bluefish**

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 can effect or be effected by other medicinal products.

Do not take Hydroxyzine Bluefish 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).
- 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 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 with food, drink and alcohol**

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

### **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.

Hydroxyzine Bluefish must not be used during pregnancy.

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

Hydroxyzine Bluefish must not be used during breast-feeding.

If Hydroxyzine Bluefish is necessary during breast-feeding, breast-feeding must be discontinued since hydroxyzine passes into breast milk.

### **Driving and using machines**

Hydroxyzine Bluefish may impair your ability to drive or operate machinery, and may cause drowsiness, reduce your attention or decrease its ability to react. The appearance of these effects is more likely at the beginning of treatment or when the dose is increased. Do not drive or operate machinery if you experience any of these effects.

### **Hydroxyzine Bluefish contains lactose**

Hydroxyzine Bluefish 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.

## **3. How to take Hydroxyzine 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.

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

**The recommended dose is:**

*For hives and itching:*

Adults and adolescents (aged 12 and above): Starting dose is 1-2 tablets of 25 mg in the evening, or as prescribed by your doctor. In adults and children over 40 kg in weight, the maximum daily dose is 100 mg per day.

Children aged 5-11 years: 1 tablet of 10 mg or 1 tablet of 25 mg in the evening, or as prescribed by the doctor. In children up to 40 kg, the maximum daily dose is 2 mg/kg/day.

*For anxiety:*

Adults: 10 mg – 50 mg daily (1-5 tablets of 10 mg or 1-2 tablets of 25 mg), divided into 2-3 doses daily. The maximum daily dose is 10 tablets of 10 mg or 4 tablets of 25 mg (100 mg per day).

For a dose below 25mg other appropriate strengths and dosage forms containing hydroxyzine should be used.

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 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 is only for the treatment of hives and itching in adolescents and children aged 5 years and older.

**Method of administration**

The tablets should be swallowed with a sufficient amount of water. The tablets can be taken with or without food. The 25 mg tablet cannot be divided into equal doses and therefore other appropriate strengths and dosage forms containing hydroxyzine should be used when required.

**If you take more Hydroxyzine Bluefish than you should**

If you have taken too much Hydroxyzine Bluefish, 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**

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

#### **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 pustolosis), 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)

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),
- 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 (transaminase, alkaline phosphate, bilirubin and glutamyl),
- itching, skin rash with redness, spots or blemishes, skin inflammation,
- urinary retention
- 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,
- bedwetting or difficulty urinating (abnormal urinary excretion),
- extreme weakness (asthenia),
- swelling of tissue due to water retention (oedema),
- weight gain.

### **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**

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

Blister:

This medicinal product does not require any special storage conditions.

HDPE bottle:

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

Store in the original package 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 Hydroxyzin Bluefish contains

- The active substance is hydroxyzine hydrochloride 25 mg.
- The other ingredients are cellulose microcrystalline, lactose monohydrate, croscarmellose sodium, colloidal anhydrous silica, talc, magnesium stearate, hypromellose 5cPs (E464), macrogol 400 (E1521), titanium dioxide (E171)

### What Hydroxyzine Bluefish looks like and contents of the pack

White to off-white, caplet shaped, biconvex, film coated tablets with score line on both sides. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

#### Blister:

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

#### Bottle:

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

250 tablets pack are 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:**

<b>Member state</b>	<b>Proposed (invented) names</b>
Sweden	Hydroxyzine Bluefish
Germany	Hydroxizin Bluefish 25 mg Filmtabletten
Denmark	Hydroxyzine Bluefish
Spain	Hidroxizina Bluefish 25mg comprimidos recubiertos con película
Iceland	Hydroxyzine Bluefish 25 mg filmuhúðaðar töflur

Norway	Hydroxyzine Bluefish
Poland	Hydroxyzinum Adamed
United Kingdom	Hydroxyzine hydrochloride 25mg Film-coated tablets

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