Package leaflet: Information for the user

Hydroxyzine hydrochloride 10 mg and 25 mg film-coated tablets

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.
- 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.

The full names of these medicines are Hydroxyzine hydrochloride 10 mg film-coated tablets and Hydroxyzine hydrochloride 25 mg film-coated tablets but they will be referred to as Hydroxyzine tablets in the rest of this leaflet.

What is in this leaflet

1. **What Hydroxyzine tablets are and what they are used for**
2. **What you need to know before you take Hydroxyzine tablets**
3. **How to take Hydroxyzine tablets**
4. **Possible side effects**
5. **How to store Hydroxyzine tablets**
6. **Contents of the pack and other information**

1. What Hydroxyzine tablets are and what they are used for

Hydroxyzine tablets contain the active substance hydroxyzine hydrochloride, which belongs to a group of medicines called antihistamines (used to treat allergic reactions). It is used in adults and children to reduce itching caused by urticaria (nettle rash) and dermatitis (eczema).

Hydroxyzine hydrochloride is also used to treat anxiety in adults.

2. What you need to know before you take Hydroxyzine tablets

Do not take Hydroxyzine tablets if you:
- are allergic (hypersensitive) to hydroxyzine hydrochloride, cetirizine, other piperazine derivatives, aminophylline or ethylenediamine, or any of the ingredients of Hydroxyzine tablets (listed in section 6)
- have had an ECG (electrocardiogram) which shows a heart rhythm problem called "QT interval prolongation"
- have or had a cardiovascular disease or if your heart rate is very low
- have low salt levels in your body (e.g. low level of potassium or of magnesium)
- are taking certain medicines for heart rhythm problems or medicines that may affect the heart rhythm (see "Other medicines and Hydroxyzine tablets")
- had someone in your close family that died suddenly of heart problems
- are an asthmatic who has suffered a bad reaction to an antihistamine in the past
- have porphyria (a disease which causes stomach pain, constipation, changes in the colour of urine, skin rashes and disturbed behaviour)
- are pregnant, trying to become pregnant or breast-feeding.

Hydroxyzine 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. If you have hereditary galactose intolerance, total lactase deficiency or glucose-galactose malabsorption you should not take this medicine.

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you take Hydroxyzine tablets.

Warnings and precautions

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

Before you take Hydroxyzine tablets tell your doctor if you suffer with:
- kidney disease or are on dialysis
- liver disease. Hydroxyzine tablets are not suitable for patients with severe liver disease or liver failure
- glaucoma (increased pressure in the eye)
- difficulty passing water e.g. due to an enlarged prostate
- digestive system or stomach problems
- myasthenia gravis (a muscle weakness disorder)
- dementia
- seizure disorders including epilepsy (fits)
- breathing problems
- bladder outflow obstruction
- hyperthyroidism (often referred to as an "overactive thyroid")
- high blood pressure (hypertension)

Your doctor may adjust your dose if you are elderly.

Hydroxyzine tablets may affect the results of some tests for allergy or asthma. Always tell your doctor or nurse that you have been given Hydroxyzine tablets recently.

If the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you take Hydroxyzine tablets.

Other medicines and Hydroxyzine tablets

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

Do not take Hydroxyzine tablets if you are taking medicine to treat:
- bacterial infections (e.g. the antibiotics 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)

It is also important that you tell your doctor if you are taking any of the following medicines:

- adrenaline or epinephrine
- barbiturates (for sleeping disorders and epilepsy)
- cimetidine (for ulcers and heartburn)
- antiemetics (drugs effective against vomiting and nausea)
- betahistine (used to treat a condition called Ménière's disease)
- anaesthetics
- muscle relaxants
- opioids (medicines for relieving severe pain)
- anticholinergic medicines, these include some medicines used for irritable bowel syndrome, asthma or incontinence
- aminophylline (for breathing problems)
- benzylpenicillin salts and chloramphenicol sodium succinate (antibiotics)
- doxorubicin hydrochloride (a chemotherapy drug)
- antidepressants, including monoamine oxidase inhibitors (MAOIs) (such as isocarboxazid or moclobemide), and tricyclics (such as amitriptyline)
- medicines to treat anxiety
- medicines that help you sleep
- benzodiazepines
- anticholinesterase medicines (such as edrophonium and neostigmine)
- antimuscarinic medicines (such as atropine)
- antiepileptic medicines
- other antihistamines

Hydroxyzine tablets with food and drink

You should not take alcohol with Hydroxyzine tablets because the sedative effects of the alcohol may be increased.

Pregnancy and breast-feeding

Do not take Hydroxyzine tablets if you are pregnant, trying to become pregnant or breast-feeding. If you become pregnant whilst taking Hydroxyzine tablets tell your doctor immediately.

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

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Hydroxyzine tablets may make you drowsy and make you feel less alert than usual for the first few days after you start taking it. If you are affected do not drive or operate machinery until this effect has worn off.

Important information about some of the ingredients of Hydroxyzine tablets

Hydroxyzine 10 mg and 25 mg 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 10 mg tablets contain sunset yellow (E110), which may cause allergic reactions.

3. How to take Hydroxyzine tablets

Always take this medicine exactly as your doctor or pharmacist has told you to. You should check with your doctor or pharmacist if you are not sure.

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

The recommended dose is:

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

For treating itching in adults

The starting dose is 25 mg at night. Your doctor may increase the dose up to 25 mg three or four times daily.

Children and adolescents

For treating itching in children

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

Children aged 6 months to 6 years:

5 mg to 15 mg daily taken throughout the day. The doctor may change this depending on the child's weight.

Children over 6 years:

15 mg to 25 mg daily which your doctor may increase up to 50 mg - 100 mg daily, taken throughout the day. The doctor may change this depending on the child's weight.

For treating anxiety in adults

The dose is 50 mg to 100 mg daily, taken throughout the day.

For patients with liver disease
Your doctor will reduce your dose by about one third if you have liver disease.
Hydroxyzine tablets are not suitable for patients with severe liver disease or liver failure.

For patients with kidney disease
Your doctor will reduce your dose by about half if you have kidney disease.

For elderly patients
In the elderly, the maximum daily dose is 50 mg per day.

If you take more Hydroxyzine tablets than you should
If you have used or taken too many Hydroxyzine tablets, immediately contact your doctor or the nearest accident and emergency department, 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.

Symptoms of an overdose can vary and may include:
- slowing of your thoughts, slurred speech and experiencing restless, involuntary or slow movements
- dry mouth, problems with your vision, fast or pounding heart beat, difficulty passing water and constipation
- slowing down of your central nervous system, which can slow your breathing and heart rate, cause you to feel drowsy or become unconscious. Or, you may experience stimulation of your central nervous system, with feelings of excitement, fits, shaking and hallucinations.

Hydroxyzine tablets can cause considerable sedation that requires treatment.

If any other medicines or substances have been taken at the same time as Hydroxyzine tablets tell the medical staff carrying out the treatment of the overdose.

If you forget to take Hydroxyzine tablets
If you forget to take a dose, take it as soon as possible, unless it is almost time to take the next dose. Do not take a double dose. Then go on as before.

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

4. Possible side effects

Do not worry. Like all medicines, Hydroxyzine tablets can cause side effects, although not everyone gets them. Hydroxyzine tablets can cause the following side effects in some people:

If you get any of the following symptoms after taking Hydroxyzine tablets, stop taking the medicine and seek immediate medical attention:
- Symptoms of a severe allergic reaction such as:
  - Swelling of the face, tongue or throat
  - Difficulties in swallowing
  - Hives and difficulties in breathing
- Severe reactions that can include serious blistering of the skin as well as the eyes, mouth and genitals
- Tremor (shakiness) or convulsions (fits)
- if you experience any problems with the heart rhythm such as palpitations, trouble breathing or loss of consciousness.

Other possible side effects of Hydroxyzine tablets include:
- drowsiness, sedation, coma, slurred speech, slowing of thought processes and movements, involuntary movements, dizziness, faintness, headache, inability to concentrate, sleep disturbances, bitter taste in mouth
- confusion, hallucinations, disorientation, unusual mood changes
- bloodshot eyes, blurred vision and difficulty in focussing
- faster or pounding heart beat
- low blood pressure, flushing
- dryness of the nose, mouth or throat, wheezing
- liver problems (symptoms include jaundice)
- difficulty or pain when passing water, blood in urine
- tiredness, general feeling of being unwell, fever, chills, muscle pain, chest tightness, achy joints
- porphyria (a rare illness which affects the metabolism), anorexia
- blood disorders
- skin rashes, swelling, itching, hives, eczema, increased sweating, hair loss, tingling, prickling, numbing of skin, pus-filled skin sores
- prolonged penile erection, impotence, early menstruation
- hearing, balance or coordination problems
- digestive system or stomach problems, feeling or being sick, diarrhoea, constipation
- weight increased (frequency unknown)

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 Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Hydroxyzine tablets

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

Do not take Hydroxyzine tablets after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

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 tablets contain

The active substance is hydroxyzine hydrochloride. Each film-coated tablet contains either 10 mg or 25 mg of hydroxyzine hydrochloride.

The other ingredients are: calcium phosphate, lactose, magnesium stearate, maize starch, silicon dioxide and sodium lauryl sulfate.

The 10 mg tablet coating contains Opadry® II Orange 85G23730. This is a mixture of poly(vinyl alcohol), talc, macrogol 3350, sunset yellow (E110), titanium dioxide (E171), iron oxide yellow (E172), quinoline yellow (E104) and lecithin (E322).

The 25 mg tablet coating contains Opadry® II Green 85G21674. This is a mixture of poly(vinyl alcohol), talc, macrogol 3350, quinoline yellow (E104), titanium dioxide (E171), brilliant blue (E133), indigo carmine (E132) and lecithin (E322).

What Hydroxyzine tablets look like and contents of the pack

Hydroxyzine hydrochloride 10 mg film-coated tablets are coloured orange imprinted with 'AX' on one side.
Hydroxyzine hydrochloride 25 mg film-coated tablets are coloured green imprinted with 'AX' on one side.

Hydroxyzine tablets are supplied in blister packs contained in a carton. The Hydroxyzine 10 mg tablet pack contains 84 film-coated tablets and the Hydroxyzine 25 mg tablet pack contains 28 film-coated tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder : DHP Healthcare Limited, 26 Pickering Street, Maidstone, Kent ME15 9RS, United Kingdom

Manufacturer: Piramal Healthcare UK Limited, Whalton Road, Morpeth, Northumberland, NE61 3YA, United Kingdom

The information in this leaflet applies only to Hydroxyzine tablets. If you have any questions or you are not sure about anything, ask your doctor or a pharmacist.

This leaflet was last revised in December 2021