

Hydroxyzine tablets

This information is a summary only. It does not contain all information about this medicine. If you would like more information about the medicine you are taking, check with your doctor or other health care provider. No rights can be derived from the information provided in this medicine leaflet.

Hydroxyzine[®] Film-coated tablets
hydroxyzine hydrochloride

Read all of this leaflet carefully before you start taking this medicine

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet please tell your doctor or pharmacist.

The information in this leaflet has been divided into the following sections:

1. What Hydroxyzine is and what it is taken for
2. Check before you take Hydroxyzine
3. How to take Hydroxyzine
4. Possible side effects
5. How to store Hydroxyzine

1. What Hydroxyzine is and what it is taken for

Hydroxyzine 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 is also used to treat anxiety in adults.

2. Check before you take Hydroxyzine

Do not take Hydroxyzine

- if you are allergic (hypersensitive) to hydroxyzine hydrochloride, cetirizine, other piperazine derivatives, aminophylline or ethylenediamine, or any of the ingredients of Hydroxyzine (see Section 6 Further information)
- if you are an asthmatic who has suffered a bad reaction to an antihistamine in the past
- if you have porphyria (a disease which causes stomach pain, constipation, changes in the colour of urine, skin rashes and disturbed behaviour)
- if you are pregnant, trying to become pregnant or breast-feeding.

Hydroxyzine contains 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, Lapp 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.

Take special care with Hydroxyzine

Before you take Hydroxyzine tell your doctor if you suffer with:

- kidney disease or are on dialysis
- liver disease. Hydroxyzine is 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
- any heart problems
- 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 may affect the results of some tests for allergy or asthma. Always tell your doctor or nurse that you have been given Hydroxyzine recently.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines as they may interfere with Hydroxyzine or Hydroxyzine may increase the effects of these 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)
- some antibiotics (benzylpenicillin salts and chloramphenicol sodium succinate)
- the chemotherapy drug doxorubicin hydrochloride
- 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
- medicines to treat psychosis
- anticholinesterase medicines (such as edrophonium and neostigmine)
- antimuscarinic medicines (such as atropine)
- antiepileptic medicines
- other antihistamines

Please tell your doctor or pharmacist if you are taking or have recently taken/used any other medicines, including medicines obtained without a prescription.

Taking with food and drink

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

Pregnancy and breast-feeding

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

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

Driving and using machines

Hydroxyzine 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 HydroxyzineUK 008 Hydroxyzine 10mg and 25mg film-coated 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 10mg film-coated tablets contain Sunset yellow (E110), which may cause allergic reactions.

3. How to take Hydroxyzine

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

The usual dose for each condition is given below:

For treating itching in adults

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

For treating itching in children

6months-6years initially 5-15mg daily increased if necessary to 50mg daily in divided doses.

Over 6 years initially 15-25mg daily increased if necessary to 50-100mg daily in divided doses

For treating anxiety in adults

The dose is 50mg to 100mg four times a day.

For patients with liver disease

Your doctor will reduce your dose by about one third if you have liver disease. Hydroxyzine is 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

Your doctor may reduce your dose if you are elderly.

What to do if you take more Hydroxyzine than you should

You probably need not worry if you have taken an extra dose of Hydroxyzine by mistake, but if you, or someone else have taken a large overdose you should tell your doctor or contact the nearest accident and emergency department immediately. Show any leftover medicines or the empty packet to the doctor.

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 can cause considerable sedation that requires treatment.

If any other medicines or substances have been taken at the same time as

Hydroxyzine tell the medical staff carrying out the treatment of the overdose.

If you forget to take Hydroxyzine

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 can cause side effects, although not everyone gets them. Hydroxyzine can cause the following side effects in some people:

If you get any of the following symptoms after taking Hydroxyzine, contact a doctor or go to the nearest hospital straight away as you may need urgent 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 skin reactions that can include blistering of the skin
- Tremor (shakiness) or convulsions (fits)

Other possible side effects of Hydroxyzine 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
- blurred vision and difficulty in focusing
- 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
- tiredness, general feeling of being unwell, fever, chills, muscle pain, chest tightness
- 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, diarrhea, constipation

If any of the side effects gets worse, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Hydroxyzine

Keep out of the reach and sight of children.

Do not take Hydroxyzine 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist on how to dispose of medicines no longer required. These measures will help protect the environment.