

PRODUCT MONOGRAPH
INCLUDING PATIENT MEDICATION INFORMATION

Hydroxyzine
Oral **25mg** HCL TABLETS
● FILM COATED

A TRANQUILIZER WITH ANTIHISTAMINE ACTION

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Hydroxyzine

Oral 25mg HCL TABLETS
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A TRANQUILIZER WITH ANTIHISTAMINE ACTION

Hydroxyzine PIL TAJ 011
PATIENT INFORMATION LEAFLET

Hydroxyzine 10mg and 25mg 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. What you need to know before you take Hydroxyzine**
- 3. How to take Hydroxyzine**
- 4. Possible side effects**
- 5. How to store Hydroxyzine**
- 6. Further information**

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. What you need to know 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 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
- Hydroxyzine PIL TAJ 011
- 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”)
 - if anyone in your close family has died suddenly of heart problems
 - 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.

Warnings and precautions

Hydroxyzine 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, 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 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
- 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.

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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.

Other medicines and Hydroxyzine

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 can affect or be affected by other medicinal products.

Do not take Hydroxyzine 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

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- anticholinesterase medicines (such as edrophonium and neostigmine)
- antimuscarinic medicines (such as atropine)
- antiepileptic medicines
- other antihistamines

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 Hydroxyzine

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 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 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
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The starting dose is 25mg at night, your doctor may increase the dose up to 25mg 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:

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

Children over 6 years:

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

For treating anxiety in adults

The dose is 50mg to 100mg 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 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

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

If you take more Hydroxyzine than you should

If you have used or taken too much Hydroxyzine, 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 Hydroxyzine PIL TAJ 011 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, 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 blistering of the skin, 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 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
- Hydroxyzine PIL TAJ 011
- 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
 - hearing, balance or coordination problems
 - digestive system or stomach problems, feeling or being sick, diarrhoea, constipation

Reporting of side effects

If you get any of the 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 internet at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Hydroxyzine

Keep this medicine out of the sight and reach 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.

6. Further information

What is in Hydroxyzine?

The active ingredient in this medicine is hydroxyzine hydrochloride.

The other ingredients are:

Calcium phosphate, lactose, magnesium stearate, maize starch, silicon dioxide and sodium lauryl sulfate.

The 10mg film-coated tablet coating contains This is a mixture of Poly(vinyl alcohol), Talc, Macrogol 3350, Sunset yellow (E110), Titanium dioxide (E171), Iron oxide yellow (E172), Quinoline yellow (E104), Lecithin (E322).

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The 25mg film-coated tablet coating contains This is a mixture of Poly(vinyl alcohol), Talc, Macrogol 3350, Quinoline yellow (E104), Titanium dioxide (E171), Brilliant blue (E133), Indigo carmine (E132), Lecithin (E322).

What Hydroxyzine looks like and contents of the pack
Hydroxyzine 10mg film-coated tablets are coloured orange imprinted with 'taj' on one side.

Hydroxyzine 25mg film-coated tablets are coloured green imprinted with 'taj' on one side.

Hydroxyzine film-coated tablets are supplied in blister packs contained in a carton.

The Hydroxyzine 10mg film-coated tablet pack contains 84 film-coated tablets and the Hydroxyzine **25mg film-coated tablet pack contains 28, 50, 100, and 500 film-coated tablets.**

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Manufactured in India by:

TAJ PHARMACEUTICALS LTD.

Mumbai, India

Unit no 214.Old Bake house, Maharashtra chambers of commerce Ltd, Fort, Mumbai - 400001

at : Ahmedabad-382213, Gujarat, INDIA.

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