

Package leaflet: information for the patient

Hydroxyzine-2HCL 10, 10 mg film-coated tablets
Hydroxyzine-2HCL 25, 25 mg film-coated tablets

Hydroxyzine dihydrochloride

Read the entire 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.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may be harmful to others, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect that is not listed in this leaflet? Then contact your doctor or pharmacist.

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1. What is Hydroxyzine-2HCL and what is it used for?

Hydroxyzine-2HCL belongs to the group of medicines known as anxiolytics. The active substance causes a mild calming effect on one hand and affects some hypersensitivity symptoms of the skin on the other hand.

Hydroxyzine-2HCL is intended for:

- the symptomatic treatment of anxiety in adults aged 18 and over
 - the symptomatic treatment of itching in adults, adolescents, and children from 6 years old.
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2. When should you not take this medicine or be extra careful with it?

When should you not take this medicine?

- you are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6 of this leaflet
- you are hypersensitive (allergic) to cetirizine (a medicine for hypersensitivity reactions), other piperazine derivatives (such as levocetirizine), aminophylline (a medicine for asthma) or ethylenediamine (a medicine for asthma) you have a disorder in the production of the iron-containing pigment of the red blood cells (porphyria)
- if your ECG (electrocardiogram) shows a heart rhythm problem called “prolonged QT interval” demonstrates
- if your body has low salt levels (e.g., low potassium or magnesium levels)

- if you are using certain medicines for heart rhythm problems or medicines that could affect the heart rhythm (see the section "Are you taking any other
- if you are using certain medications for heart rhythm problems or medications that could affect the heart rhythm (see the section "Are you using any other medications?")
- if someone in your immediate family has suddenly died of a heart condition.

When should you be extra careful with this medicine?

Contact your doctor before taking this medicine.

When you are having an allergy test (skin, lungs), you must stop using Hydroxyzine-2HCL 5 days before this test. The results of the test can be affected by Hydroxyzine-2HCL.

Hydroxyzine-2HCL may be associated with an increased risk of arrhythmias that can be life-threatening. Therefore, tell your doctor if you have a heart condition or if you are using other medications, including over-the-counter medications.

During your treatment with Hydroxyzine-2HCL, seek immediate medical help if you experience heart problems such as palpitations, breathing difficulties, or loss of consciousness. The treatment with hydroxyzine should then be discontinued.

Be cautious when you have an increased risk of developing:

- seizures
- cataracts
- obstructions in the gastrointestinal tract
- obstructions in the urinary tract
- muscle weakness
- dementia
- irregular heart function.

Children

In children, seizures have been reported more frequently than in adults.

Do not give this medicine to children under 6 years old, as they may not be able to swallow

Elderly

Due to prolonged duration of action, the elderly are started on half of the usual dosage (see section 3).

Patients with impaired kidney function

If you have impaired kidney function, the usual dosage should be reduced (see section 3).

Patients with impaired liver function

If you have impaired liver function, the usual dosage should be reduced (see section 3).

Contact your doctor if any of the above situations apply to you or have applied in the past.

Are you taking any other medicines?

Are you taking any other medicines besides Hydroxyzine-2HCL, have you done so recently, or are you planning to do so soon? Then tell your doctor. This also applies to medicines for which you do not need a prescription. Hydroxyzine-2HCL can affect other medicines or be affected by them.

Do not use Hydroxyzine-2HCL if you are taking medicines for the treatment of:

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

Hydroxyzine-2HCL can enhance the effects of the following medications:

- barbiturates (sleeping pills)
- narcotics (anesthetics)
- non-narcotic analgesics (painkillers)
- betahistine (a medication for Ménière's disease)
- tricyclic antidepressants and monoamine oxidase inhibitors (medications for depression)
- beta-blockers (medications for high blood pressure, certain heart conditions, or increased eye pressure)
- class 1C anti-arrhythmics (medications for heart rhythm disorders).

Hydroxyzine-2HCL counteracts the effects of:

- phenytoin (a medication for epilepsy)
- adrenaline (a medication that enhances heart function).

Caution is advised when using Hydroxyzine-2HCL concurrently with cimetidine (medication for stomach issues) and cetirizine (medication for allergic reactions).

What should you be aware of with food, drink, and alcohol?

The tablets can be taken with or without food. Do not use Hydroxyzine-2HCL concurrently with alcohol. Hydroxyzine-2HCL can enhance the effect of alcohol.

Pregnancy, breastfeeding, and fertility

Hydroxyzine-2HCL should only be used during pregnancy if strictly necessary. During the breastfeeding period, Hydroxyzine-2HCL should not be used. Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medication.

Driving ability and the use of machines

Hydroxyzine-2HCL can reduce your reaction time and concentration ability.

Concurrent use with alcohol or other medications that affect the nervous system is not recommended, as this can exacerbate the effects.

The use of Hydroxyzine-2HCL can result in drowsiness, sleepiness, dizziness, and headache (see section 4).

Consider your reaction to this medication if you plan to drive a vehicle, engaging in hazardous activities or operating machinery.

Hydroxyzine-2HCL contains lactose

If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before taking this medicine.

3. How do you take this medicine?

Always take this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

Hydroxyzine-2HCL should be used at the lowest effective dose and for the shortest possible duration.

Adults

- For symptomatic treatment of anxiety:
50 mg/day in three separate doses of 12.5 (half tablet) - 12.5 (half tablet) - 25 mg (one tablet). It is at the discretion of the prescriber whether a larger dose should be taken in the evening. In more severe cases, the dosage can be increased to 100 mg per day. The maximum daily dose is 100 mg per day.
- For symptomatic treatment of itching:
Initial dose of 25 mg to be taken at bedtime, if necessary followed by doses of 25 mg 3 to 4 times a day.
In adults, the maximum daily dose is 100 mg per day,

Use in children

Other form(s) of this medicine may be suitable for children; ask your doctor or pharmacist.

For symptomatic treatment of itching:

In children aged 6 years and older: 1 mg/kg/day to 2 mg/kg/day in multiple doses.

The maximum daily dose in children weighing no more than 40 kg is 2 mg/kg/day. The maximum daily dose in children weighing more than 40 kg is 100 mg/day.

Elderly

Due to prolonged duration of action, the elderly are started on half of the usual dosage.

In the treatment of anxiety, the dosage is 25 mg per day, divided into 2 doses of 12.5 mg in the morning and 12.5 mg in the evening. In more severe cases, the

dosage can be increased to 50 mg per day.

In the treatment of itching, the initial dose is 12.5 mg, to be taken at bedtime, if necessary followed by doses of 12.5 mg 3 to 4 times a day.

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

Patients with impaired kidney function

If you have impaired kidney function, the usual dosage should be reduced. For example, to half in case of moderately impaired kidney function and to a quarter in case of severely impaired kidney function.

Patients with impaired liver function

If you have impaired liver function, the usual dosage should be reduced by one third.

For the treatment of anxiety, the dosage is 30 mg per day, divided into 3 doses of 10 mg in the morning, 10 mg in the afternoon, and 10 mg in the evening. In more severe cases, the dosage can be increased to 60 mg per day.

For the treatment of itching, the initial dose is 12.5 mg, to be taken at bedtime, if necessary followed by doses of 12.5 mg 3 to 4 times a day.

When and how should you take Hydroxyzine-2HCL?

Hydroxyzine-2HCL is best taken after meals. The tablets should be swallowed with a sufficient amount of water.

The tablets can be divided into equal doses.

Have you taken too much of this medicine?

Symptoms that may occur if you have taken too much Hydroxyzine-2HCL include:

- nausea
- vomiting
- increased heart rate (tachycardia)
- fever
- drowsiness
- trembling muscle movement (tremor)
- confusion
- hallucinations
- reduced consciousness
- hypoventilation (respiratory depression)
- seizures (convulsions)
- lowered blood pressure (hypotension)
- irregular heart function (arrhythmia including bradycardia)
- deep unconsciousness (deep coma)
- cardiac and respiratory arrest (cardio-respiratory collapse).

If you have used or taken too much Hydroxyzine-2HCL, contact your doctor or pharmacist immediately, especially if a child has taken too much. In case of overdose, symptomatic

treatment may be initiated. ECG monitoring may be performed due to the possibility of a heart rhythm disorder such as QT interval prolongation or torsade de pointes.

Have you forgotten to take this medicine?

Do not take a double dose to make up for a forgotten dose or if you have taken less than was prescribed by your doctor. Continue taking the amount prescribed by your doctor at the usual time.

If you stop taking this medicine

If you suddenly stop using Hydroxyzine-2HCL without your doctor's advice the symptoms you had before the treatment may return with the same severity.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like any medicine, this medicine can also have side effects. Not everyone will experience them.

Side effects can:

occur very frequently (may occur in more than 1 in 10 patients)

occur frequently (may occur in 1 in 10 patients)

occur sometimes (may occur in 1 in 100 patients)

occur rarely (may occur in 1 in 1,000 patients)

occur very rarely (may occur in 1 in 10,000 patients)

unknown (cannot be determined from the available data)

The following side effects may occur:

Blood and lymphatic system disorders

Unknown: a decreased number of platelets

Immune system disorders

Rare: hypersensitivity

Very rare: severe hypersensitivity reaction (anaphylactic shock)

Psychiatric disorders

Sometimes: agitation, confusion

Rarely: disorientation, hallucination

Unknown: depression

Nervous system disorders

Very common: drowsiness

Common: headache, drowsiness

Sometimes: dizziness, insomnia, trembling muscle movement (tremor)

Rarely: seizure, movement disorder (dyskinesia)

Unknown: sensory disturbance, syncope

Eye disorders

Rarely: visual disturbances, blurred vision

Heart disorders

Rarely: palpitations

Unknown: ventricular arrhythmias (e.g., torsade de pointes), QT interval prolongation

Vascular disorders

Rarely: low blood pressure

Respiratory, thoracic, and mediastinal disorders

Very rarely: airway muscle spasm

Gastrointestinal disorders

Common: dry mouth

Sometimes: nausea

Rarely: constipation, vomiting

Unknown: diarrhea

Liver and biliary disorders

Rarely: abnormal liver function tests

Unknown: hepatitis

Skin and subcutaneous tissue disorders

Rarely: itching, rash, hives, dermatitis

Very rarely: sudden swelling in the skin and mucous membranes [for example in face, arms and/or legs, lips, tongue, larynx], breathing difficulties and/or itching and rash (so-called angioneurotic edema), increased sweating, round reddish-brown spots (erythema fixatum), superficial blisters filled with pus (exanthematous pustulosis),

multiform red skin (erythema multiforme), red, slightly raised irregular spots (Stevens-Johnson syndrome)

Unknown: blistering (e.g., toxic epidermal necrolysis, pemphigoid)

Renal and urinary disorders

Rarely: urinary retention

Unknown: painful and difficult urination

General disorders and administration site conditions

Often: fatigue

Sometimes: malaise, fever

Unknown: body weakness

The following side effects may also occur with Hydroxyzine-2HCL: aggression, tics, muscle tone disorder, spasmodic eye movements, bedwetting, edema, weight gain.

Stop using the medicine and seek immediate medical help if you

experience heart rhythm problems such as palpitations, breathing difficulties, or loss of consciousness.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Store below 25°C. Keep in the original packaging to protect from light.

Do not use this medicine after the expiry date. You can find it on the bottle after 'EXP'. It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. If you dispose of medicines correctly manner, they are destroyed in the correct way and do not end up in the environment.

6. Contents of the package and other information

What substances are in this medicine?

- The active substance in this medicine is hydroxyzine dihydrochloride. The film-coated tablets contain 10 or 25 mg of hydroxyzine dihydrochloride, respectively.
- The other substances in this medicine are:
 - film-coated tablet of 10 mg: lactose, maize starch, talc (E553B), povidone (E1201), calcium stearate (E470A), eudragit E, polyethylene glycol 6000, titanium dioxide (E171).
 - film-coated tablet of 25 mg: lactose, microcrystalline cellulose, magnesium stearate (E470B), colloidal silicon dioxide (E551), titanium dioxide (E171), hydroxypropylmethylcellulose (E464), macrogol 400.

What does Hydroxyzine-2HCL look like and what is in a package?

White, round film-coated tablets of 10 mg packed in a plastic bottle of 250 tablets.

White, oblong film-coated tablets of 25 mg with a score line packed in a plastic bottle of 250 tablets.

Marketing authorization holder and manufacturer

Marketing authorization holder:

UCB Pharma B.V.

Hoge Mosten 2

4822 NH Breda
Manufacturer:
UCB Pharma NV
Chemin du Foriest
B-1420 Eigenbrakel
Belgium

Marketing authorization number

Hydroxyzine-2HCL 10 is registered under RVG 50109.
Hydroxyzine-2HCL 25 is registered under RVG 50110.

This leaflet was last approved in January 2023.

Other sources of information

More information about this medicine can be found on the CBG website (www.cbg-meb.nl).