

## **Hydroxyzine hydrochloride 10 mg, 25 mg tablets with a film coating.**

### **What is Hydroxyzine-2HCL and what is it used for?**

Hydroxyzine-2HCL belongs to the group of medicines called anxiolytics. The active ingredient causes a mild calming effect on one hand, and on the other hand, it has an effect on some hypersensitivity reactions of the skin.

Hydroxyzine-2HCL is intended for:

- the symptomatic treatment of anxiety in adults aged 18 years and older
- the symptomatic treatment of itching in adults, adolescents, and children aged 6 years and older.

### **When should you not take this medicine or use it with extra caution?**

#### **When should you not take this medicine?**

- if you are allergic to any of the substances in this medicine. You can find these substances
- if you are hypersensitive (allergic) to cetirizine (a medicine used for hypersensitivity reactions), other piperazine derivatives (such as levocetirizine), aminophylline (a medicine used for asthma), or ethylenediamine (a medicine used for asthma)
- if you have a disorder in the production of the iron-containing pigment of the red blood cells (porphyria)
- if your electrocardiogram (ECG) shows a heart rhythm problem called "prolonged QT interval"
- if you have (had) a heart or vascular disease or if your heart rate is very low
- if your body has low levels of salt (e.g. low potassium or magnesium levels)
- if you are taking certain medicines for heart rhythm problems or medicines that could affect your heart rhythm (see section "Are you taking any other medicines?")
- if someone in your close family has suddenly died of a heart disease.

#### **When should you be extra careful with this medicine?**

If you are scheduled to undergo an allergy test (skin, lungs), you should stop taking Hydroxyzine-2HCL 5 days before the test. Hydroxyzine-2HCL may affect the results of the test. Hydroxyzine-2HCL may be associated with an increased risk of life-threatening heart rhythm disorders. Therefore, inform your doctor if you have a heart condition or if you are taking other medications, including non-prescription drugs.

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

Be careful if you have an increased risk of developing: • seizures, • cataracts, • blockages in the gastrointestinal tract, • blockages in the urinary tract, • muscle weakness, • dementia, • irregular heart function.

**Children:** Seizures have been reported more frequently in children than in adults. Do not give this medicine to children under 6 years of age as they may not be able to swallow the tablets.

**Elderly:** Due to a prolonged duration of action, the usual dose for elderly patients is started at half the usual dose.

Patients with impaired kidney function.

If you have impaired kidney function, the usual dose should be reduced.

**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 to you in the past.

#### **Are you taking any other medicines?**

If you are taking other medicines besides Hydroxyzine-2HCL, have taken them recently, or plan to take them in the near future, tell your doctor. This includes medicines that do not require a prescription. Hydroxyzine-2HCL may affect or be affected by other medicines.

Do not use Hydroxyzine-2HCL if you are taking medicines for the treatment of: • bacterial infections (e.g., antibiotics such as 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), • allergies, • malaria (e.g., mefloquine, hydroxychloroquine), • cancer (e.g., toremifene, vandetanib), • drug abuse or severe pain (methadone).

Hydroxyzine-2HCL may enhance the effect of the following medicines: • barbiturates (sedatives), • narcotics (analgesics), • non-narcotic analgesics (painkillers), • betahistine (a medicine for Meniere's disease), • tricyclic antidepressants and monoamine oxidase inhibitors (medicines for depression), • beta-blockers (medicines for high blood pressure, certain heart conditions, or increased intraocular pressure), • class 1C antiarrhythmics (medicines for heart rhythm disorders).

Hydroxyzine-2HCL counteracts the effects of: • phenytoin (a medicine for epilepsy), • adrenaline (a medicine that promotes heart function).

Use caution when taking Hydroxyzine-2HCL together with cimetidine (a medicine for stomach complaints) and cetirizine (a medicine for allergic reactions).

#### **What should you be aware of regarding food, drinks, and alcohol?**

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

### **Pregnancy, Breastfeeding, and Fertility**

Hydroxyzine-2HCL may only be used during pregnancy if strictly necessary. It should not be used during breastfeeding. If you are pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding, please consult your doctor or pharmacist before using this medicine.

### **Driving and operating machinery**

Hydroxyzine-2HCL may reduce your reaction time and concentration. Concurrent use with alcohol or other medicines affecting the nervous system is not recommended as it can worsen the effects. Use of Hydroxyzine-2HCL may result in drowsiness, sleepiness, dizziness, and headache (see section 4). Take into account your response to this medicine if you plan to drive, engage in hazardous activities, or operate machinery.

Hydroxyzine-2HCL contains lactose. If your doctor has told you that you have an intolerance to certain sugars, please consult your doctor before taking this medicine.

### **How to take this medicine**

Always take this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, please consult your doctor or pharmacist. Hydroxyzine-2HCL should be used at the lowest effective dose and for the shortest possible time.

### **Adults**

**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 up to the prescriber to decide whether a larger dose should be taken in the evening. In more severe cases, the dosage may be increased to 100 mg per day. The maximum daily dose is 100 mg per day.

**Symptomatic treatment of itching:** Starting 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.

**Symptomatic treatment of itching:** In children aged 6 years and older: 1 mg/kg/day to 2 mg/kg/day in several 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 usual dose for elderly patients is half the usual dose.

When treating 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 may be increased to 50 mg per day.

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

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

Patients with decreased kidney function should have the usual dosage reduced. For example, the dosage should be halved in case of moderate kidney impairment and reduced to one-quarter in case of severe kidney impairment.

Patients with decreased liver function should reduce the usual dosage by one-third.

When treating 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 may be increased to 60 mg per day.

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

### **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.

### **What should you do if you take too much of this medicine?**

Symptoms that may occur if you have taken too much Hydroxyzine-2HCL are: • nausea, • vomiting, • increased heart rate (tachycardia), • fever, • drowsiness, • trembling muscle movements (tremor), • confusion, • hallucinations, • decreased consciousness, • hypoventilation (respiratory depression), • seizures (convulsions), • decreased blood pressure (hypotension), • irregular heart rate (arrhythmia, including bradycardia), deep unconsciousness (deep coma), • cessation of heart and breathing (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 can 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.

### **Did you forget to take this medicine?**

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

### **If you stop taking this medicine?**

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

## Possible side effects

Like any medicine, this medicine can have side effects. Not everyone experiences them.

Side effects can occur:

- Very often (may affect more than 1 in 10 patients)
- Often (may affect 1 in 10 patients)
- Sometimes (may affect 1 in 100 patients)
- Rarely (may affect 1 in 1,000 patients)
- Very rarely (may affect 1 in 10,000 patients)
- Unknown (cannot be determined from available data)

The following side effects may occur:

**Immune system disorders:** Rare: hypersensitivity, Very rare: severe hypersensitivity reaction (anaphylactic shock)

**Psychiatric disorders:** Sometimes: agitation, confusion, Rare: disorientation, hallucination

**Nervous system disorders:** Very common: drowsiness: Common: headache, dizziness: Sometimes: insomnia, trembling muscle movement (tremor), Rare: seizure, movement disorder (dyskinesia) disorder in sensation, syncope, Eye disorders, Rare: vision disorders, blurred vision

**Cardiac disorders:** Rare: palpitations

**Vascular disorders:** Rare: hypotension, Respiratory, thoracic and mediastinal disorders, Very rare: spasm of the muscles in the airway

**Gastrointestinal disorders:** Common: dry mouth, Uncommon: nausea, Rare: constipation, vomiting

**Hepatobiliary disorders:** Rare: abnormal liver function tests

**Skin and subcutaneous tissue disorders:** Rare: pruritus, rash, urticaria, dermatitis, Very rare: sudden swelling of the skin and mucous membranes [e.g. in the face, arms and/or legs, lips, tongue, throat], difficulty breathing and/or itching and rash (called angioedema), increased sweating, round reddish-brown spots (erythema fixatum), superficial pustules (exanthemateuze pustulose), polymorphic redness of the skin (erythema multiforme), red, slightly elevated irregular spots (Stevens-Johnson syndrome)

**Renal and urinary disorders:** Rare: urinary retention

**General disorders and administration site conditions:** Common: fatigue, Uncommon: malaise, fever

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

Stop using the medicine and seek immediate medical attention if you experience heart rhythm problems such as palpitations, breathing problems, or loss of consciousness.

## How to store this medicine?

Keep out of the sight and reach of children.

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

Do not use this medicine after the expiry date which is stated on the bottle and carton after "EXP". The expiry date refers to the last day of that month. Do not dispose of medicines in wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.