

## **Package leaflet: Information for the patient**

### **Hydroxyzine Orifarm 10 mg film-coated tablets Hydroxyzine Orifarm 25 mg film-coated tablets**

hydroxyzine hydrochloride

**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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

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

#### **1. What Hydroxyzine Orifarm is and what it is used for**

##### **What is Hydroxyzine Orifarm?**

Hydroxyzine Orifarm belongs to a group of medicines called sedating antihistamines. It suppresses certain functions in the brain without creating a habit. It also blocks histamine, a substance found in body tissues, which is responsible for allergic reactions.

##### **What is it used for?**

Hydroxyzine Orifarm is used in treatment of:

- anxiety in adults where no other medication is suitable,
- hives and itching caused by allergic reactions.

For anxiety, the effect is noticeable after about 15 minutes and remains for around 12 hours. For itching and hives, the effect is reached after about 1 hour and remains for at least 24 hours.

#### **2. What you need to know before taking Hydroxyzine Orifarm**

##### **Do not take Hydroxyzine Orifarm**

- if you are allergic to hydroxyzine hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to cetirizine (medicine to treat allergies), aminophylline (medicine to treat asthma or other lung diseases), ethylenediamine (a component of aminophylline) or other piperazine derivatives (closely related active substances of other medicines).
- if you have an inherited disease (porphyria) characterized by an accumulation of toxic compounds (porphyrins) in the body.
- 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
- 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 Orifarm”)
- if anyone in your close family has died suddenly of heart problems
- if you are pregnant or are breast-feeding.

### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Hydroxyzine Orifarm:

- if you have a kidney or a liver disease. You might need a lower dose.
- if you have an increased risk of getting fits (seizures).
- if you have any risk factors for stroke, such as high blood pressure, smoking or obesity.
- if you have an increase in pressure in the eye (glaucoma).
- if you have problems to urinate.
- if you have a slow intestinal function.
- if you have a severe muscle weakness (myasthenia gravis).
- if you have dementia.

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

Dry mouth can be a side effect of Hydroxyzine Orifarm use. It is therefore important that you have a good oral hygiene during treatment with Hydroxyzine Orifarm.

If you are undergoing allergy testing, treatment with Hydroxyzine Orifarm should be discontinued at least 5 days before the testing. Ask your doctor for advice.

### **Older people**

Caution is required if you are elderly and you might need a lower dose. The duration of the treatment should be as short as possible.

### **Other medicines and Hydroxyzine Orifarm**

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

Do not take Hydroxyzine Orifarm 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, hydroxychloroquine)
- cancer (e.g. toremifene, vandetanib)
- drug abuse or severe pain (methadone)

Also, tell your doctor if you are taking:

- betahistine used to treat Meniere’s disease (problems with balance and hearing),
- phenytoin used for the treatment of fits (seizures),
- adrenaline used to treat severe allergic reactions.
- medicines used to treat anxiety or help you sleep,

- anticholinergic medicines for the treatment of e.g. irritable bowel syndrome (digestive disorders) and asthma.
- cimetidine used for the treatment of stomach problems. This may increase the level of Hydroxyzine Orifarm in your blood.
- monoamine oxidase inhibitors used for the treatment of depression and Parkinson's disease,
- thiazide diuretics (used to treat e.g. high blood pressure). They may increase the risk for irregular heart rate.

### **Hydroxyzine Orifarm with food, drink and alcohol**

The tablets can be taken with or without food.

You should not drink alcohol when taking Hydroxyzine Orifarm because this combination may enhance the effects of Hydroxyzine Orifarm and thereby the risk of side effects.

### **Pregnancy and breast-feeding**

#### *Pregnancy*

Do not take Hydroxyzine Orifarm if you are pregnant or think you may be pregnant. Talk to your doctor if you are planning to have a baby.

Hydroxyzine, the active substance in Hydroxyzine Orifarm, passes over to the foetus. There is a risk of affecting the foetus.

#### *Breast-feeding*

Do not take Hydroxyzine Orifarm if you are breast-feeding.

Stop breast-feeding if treatment with Hydroxyzine Orifarm is necessary. Ask your doctor for advice.

### **Driving and using machines**

Hydroxyzine Orifarm may affect your reactions and your ability to concentrate. Be cautious when driving or operating machinery. It is your responsibility to assess if you are capable to drive or use machines when you need alertness.

### **Hydroxyzine Orifarm 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.

## **3. How to take Hydroxyzine Orifarm**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

**Important:** your doctor will choose the dose that is right for you. Do not change your dose without consulting your doctor first.

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

25 mg tablet: The tablet can be divided into equal doses.

The recommended dose is:

#### **Hives and itching:**

- Adults and adolescents aged 12 and above: Starting dose is 1 or 2 tablets of 25 mg in the evening.
- Children aged 5-11 years: 1 tablet of 10 mg or 1 tablet of 25 mg in the evening. The doctor will inform you of the correct dose.

See below "maximum daily dose for all indications".

If you/your child require a dose below 10 mg or if you/your child have difficulty swallowing the tablets, other medicinal products containing hydroxyzine may be more appropriate. Talk to your doctor.

#### **Anxiety in adults:**

- Adults: recommended dose is 1 to 5 tablets of 10 mg 2-3 times daily or 1-2 tablets of 25 mg 2-3 times daily. The maximum daily dose is 10 tablets of 10 mg or 4 tablets of 25 mg.

See below “maximum daily dose for all indications”.

#### **Maximal daily dose for all indications:**

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

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

Medical treatment of anxiety should always be taken as a supplement to other types of treatment. Treatment should be started, followed up and completed by the same physician.

#### **Particular groups of patients:**

- Older people: for older people, it is advised to start with half the recommended dose. The lowest possible dose should be selected in the treatment of older patients. The maximum daily dose is 50 mg per day.
- Patients with kidney problems: dosage should be reduced in patients with moderate or severe kidney problems.
- Patients with liver problems: in patients with reduced liver activity, it is recommended to reduce the daily dose.

#### **Method of administration**

The tablets should be swallowed with a sufficient amount of water. The tablets can be taken with or without food. The 25 mg tablet can be divided into equal doses.

#### **If you take more Hydroxyzine Orifarm than you should**

If you have taken too many Hydroxyzine Orifarm immediately contact [to be completed nationally], 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.

#### **If you forget to take Hydroxyzine Orifarm**

Do not take a double dose to make up for a forgotten tablet. It will depend on your given dosage, whether you should take your forgotten dose or take your next dose at the usual time. Ask your doctor.

#### **If you stop taking Hydroxyzine Orifarm**

If you decide not to take Hydroxyzine Orifarm anymore, your condition can become worse. Talk to your doctor before you discontinue treatment with Hydroxyzine Orifarm.

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

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking the medicine and seek immediate medical attention if you experience

- any problems with the heart rhythm such as palpitations, trouble breathing or loss of consciousness. (frequency not known, cannot be estimated from the available data)
- swelling of face, lips, tongue and/or throat, sometimes with difficulties in breathing or swallowing (angioedema) (Very rare side effects that may affect up to 1 in 10,000 people)
- widespread rashes with blisters (acute generalised exanthematous pustolosis), ring-shaped, red and often blistering rashes – common on hands and feet (erythema multiforme), mucosal and skin inflammation in

combination with high fever (Stevens-Johnson syndrome) (Very rare side effects that may affect up to 1 in 10,000 people)

- heavy shelling and rejection of the skin (toxic epidermal necrolysis) (frequency not known, cannot be estimated from the available data).

Other side effects that may occur:

*Very common: may affect more than 1 in 10 people:*

- sleepiness.

*Common: may affect up to 1 in 10 people:*

- headache,
- tiredness,
- dry mouth,
- sedation.

*Uncommon: may affect up to 1 in 100 people:*

- agitation, confusion,
- dizziness, sleeplessness, tremor,
- feeling sick (nausea),
- feeling unwell, fever.

*Rare: may affect up to 1 in 1,000 people:*

- allergic (hypersensitivity) reactions,
- disorientation, hallucinations (seeing things that are not there),
- fits (seizures), movement disorder,
- accommodation disturbances of the eye (hard to focus), blurred vision,
- cardiac arrest, effects on heart rate, fast heart,
- low blood pressure,
- constipation, vomiting,
- elevated liver enzyme values (can be seen in blood tests),
- itching, hives, marks or blisters, inflammation of the skin,
- problems to urinate.

*Very rare: may affect up to 1 in 10,000 people:*

- anaphylaxis (potentially deadly allergic reaction),
- constrictions in the respiratory passage.

*Not known: frequency cannot be estimated from the available data:*

- reduction of number of platelets,
- inflammation of the liver,
- aggression, depression, repeated involuntary muscle twitching (tics),
- abnormal prolonged muscle contractions, sensation of tickling, tingling or numbness,
- irregular heart rhythm and changes on your electrocardiogram in connection to this (QT prolongation, Torsade de Pointes),
- uncontrolled circular movements of the eyes,
- diarrhoea,
- bedwetting,
- extreme tiredness, swelling of tissue due to water retention (oedema),
- weight gain,
- fainting,
- pemfigoid (blisters on the arms, legs, stomach and mucous membranes).

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **the national reporting system listed in Appendix V**. By reporting side effects, you can help provide more information on the safety of this medicine.

## **5. How to store Hydroxyzine Orifarm**

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

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

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 Orifarm contains**

- The active substance is hydroxyzine hydrochloride respective 10 mg or 25 mg.
- The other excipients are:  
*Core:* Lactose monohydrate, calcium phosphate tribasic, pregelatinized starch, sodium laurilsulfate, colloidal anhydrous silica, magnesium stearate.  
*Film-coating:* Macrogol, hypromellose, titanium dioxide (E171).

### **What Hydroxyzine Orifarm looks like and contents of the pack**

10 mg: White to off-white, circular, biconvex film-coated tablets and plain on both sides (diameter 5.3-5.7 mm, thickness 2.7-3.3 mm).

25 mg: White to off-white, circular, biconvex film-coated tablets with break line on one side (diameter 7.8-8.2 mm, thickness 3.5-4.1 mm).

PVC/PVDC/aluminium blisters: 25 and 100 tablets.

HDPE container: 250 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

[To be completed nationally]

**This medicinal product is authorised in the Member States of the EEA under the following names:**

<{Name of the Member State}> <{Name of the medicinal product}>

<{Name of the Member State}> <{Name of the medicinal product}>

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