

Patient Information Leaflet
Ucerax®
10mg/5ml Syrup
Hydroxyzine dihydrochloride

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.
- In this leaflet Ucerax Syrup 10 mg/5 ml is called Ucerax Syrup.

In this leaflet:

1. What Ucerax Syrup is for
2. Before you take Ucerax Syrup
3. How to take Ucerax Syrup
4. Possible side effects
5. How to store Ucerax Syrup
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1. What Ucerax Syrup is for

Ucerax Syrup belongs to a group of medicines called sedating antihistamines. It is thought to work by inhibiting some activity in the brain.

Ucerax Syrup is used to treat:

- Anxiety in adults
- Itching (pruritus) caused by allergic reactions in adults and children.

2. Before you take Ucerax Syrup

Do not take Ucerax Syrup if:

- You are allergic to hydroxyzine hydrochloride or any of the other ingredients of Ucerax Syrup (listed in Section 6)
- You are allergic to cetirizine, other piperazine derivatives, aminophylline or ethylenediamine
- You are pregnant or breastfeeding
- You have a condition called porphyria. (A blood disease that can cause stomach pain, vomiting and mental disturbances such as depression.)
- You have a condition known as prolonged QT interval causing irregular heart beat and/or palpitations.
- Your ECG (electrocardiogram) shows a heart rhythm problem called “QT interval prolongation”
- You have or had a cardiovascular disease or if your heart rate is very low
- You have low salt levels in your body (e.g. low level of potassium or of magnesium)
- You are taking certain medicines for heart rhythm problems or medicines that may affect the heart rhythm (see “Other medicines and Ucerax”)
- Anyone in your close family has died suddenly of heart problems

If any of the above applies to you talk to your doctor or pharmacist.

Warnings and precautions

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

Check with your doctor or pharmacist before taking Ucerax Syrup if:

- You suffer from fits (convulsions)
- You have an eye disease called glaucoma
- You have problems urinating
- You have kidney disease
- You have stomach problems
- You have dementia (a loss of mental abilities such as remembering)
- You have a condition called myasthenia gravis which weakens the muscles
- You have heart problems
- You have problems with your liver
- You have constipation
- You have a condition which means you have to be careful having sugar (such as diabetes or problems with your body digesting or absorbing sugar). This medicine contains 9.4 grams of sugar (sucrose) in every 12.5 ml dose. It may also be harmful to the teeth.
- This medicine contains small amounts of ethanol (alcohol) less than 100 mg per 25 ml dose.
- You have an imbalance of potassium or magnesium ions in your blood.

Other medicines and Ucerax

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. Ucerax can affect or be affected by other medicinal products.

Do not take Ucerax 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)

Tell your doctor if you are taking any of the following medicines:

- Betahistine used to treat Meniere's disease (problems with balance and hearing)
- Phenytoin used for the treatment of fits (convulsions)
- Adrenaline used to treat severe allergic reactions Ucerax Syrup may reduce the effect of these medicines.

Also tell your doctor if you are taking:

- Medicines used to treat anxiety or help you sleep
- Anticholinergic medicines for the treatment of irritable bowel syndrome
- Drugs that alter the rhythm of your heartbeat. Ucerax Syrup may increase the effect of these medicines.

Tell your doctor if you are taking:

- Cimetidine used for the treatment of stomach problems. This may increase the level of Ucerax Syrup in your blood
- Monoamine oxidase inhibitors used for the treatment of depression
- Any other medicines including medicines obtained without a prescription.

Tell your doctor that you are taking Ucerax Syrup if you are going to have allergy testing or a chest medical examination (for asthma) in the next 5 days. Ucerax Syrup can affect the test results.

Taking Ucerax Syrup with food and drink

Do not drink alcohol whilst you are taking Ucerax Syrup

Pregnancy and breastfeeding

Do not take Ucerax Syrup if you are pregnant, trying to become pregnant or breastfeeding.

Driving and using machines

Do not drive or operate machines if you take Ucerax Syrup. Ucerax Syrup may affect your ability to react and concentrate.

3. How to take Ucerax Syrup

Always take Ucerax Syrup exactly as your doctor has told you.

Important: Your doctor will choose the dose that is right for you. Your dose and when to take it will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.

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

Adults

In adults and children over 40 kg in weight, the maximum daily dose is 100 mg (50 ml) per day in all indications.

For anxiety:

- The usual dose is 6.25 ml at breakfast, 6.25 ml at lunch and 12.5 ml in the evening
 - Your doctor may increase this to a maximum of 50 ml a day taken in divided doses (for example, 12.50 ml – 12.5 ml – 25 ml a day).
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For pruritus (itchiness of the skin):

- The usual dose is 12.5 ml before going to bed
- Your doctor may increase this to 12.5 ml three or four times a day
- Do not take more than 50 ml of syrup at any one time.
- Do not take more than 50 ml of syrup in one day.

Children

In children up to 40 kg, the maximum daily dose is 2 mg (1ml) /kg/day.

For pruritus in children (over 12 months) up to 40 kg in weight:

- The usual dose is 0.5 ml per kg of body weight a day, in divided doses.
- Your doctor may increase this to a maximum of 1 ml per kg of body weight a day, in divided doses.

The elderly

In the elderly, the maximum daily dose is 50 mg (25 ml) per day.

- The usual starting dose is 6.25 ml before going to bed.
- Your doctor will tell you how much and when to take your syrup.

People with liver and kidney problems

- Your doctor may choose a lower daily dose for you
- Your doctor will tell you how much syrup to take and when to take them.

If you take more Ucerax Syrup than you should

If you have used or taken too much Ucerax Syrup, immediately contact or attend your nearest hospital 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.

If you take more Ucerax Syrup than you should you may feel sick or be sick, feel sleepy, confused, or have heart palpitations, fever, unreactive pupils, the shakes, hallucinations, breathing problems, fits or low blood pressure. An overdose can lead to a coma and be fatal.

If you forget to take Ucerax Syrup

Do not take a double dose to make up for a missed dose. Simply take your next dose as planned. If you have any further questions about the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines Ucerax Syrup can cause side effects, although not everybody gets them.

Stop taking Ucerax Syrup and seek immediate medical help if you have any of the following symptoms:

- An allergic reaction with difficulty in breathing, swelling or fever.
- A severe allergic reaction (also known as Stevens- Johnson syndrome) causing a fever, inflammation, blistering and ulceration of the skin which can result in the surface layer of the skin peeling away.
- Fits (convulsions).
- Your heart beat faster
- Your chest tightening and experience difficulty breathing.
- Your vision becomes blurred and you have difficulty focussing.
- An inability to pass water.
- Any problems with the heart rhythm such as palpitations, trouble breathing or loss of consciousness.

Other side effects

Very common side effects (affects more than 1 in 10 people):

- feeling sleepy

Common side effects (affects less than 1 in 10 people)

- dry mouth, feeling tired, headache

Uncommon side effects (affects less than 1 in 100 people)

- dizziness, difficulty sleeping, unable to concentrate, weakness
- feeling sick, constipation
- **Not known** (frequency cannot be estimated from the available data) being sick, malaise (a feeling of discomfort or feeling unwell)
- involuntary limb movements, tremor
- disorientation, hallucination, confusion, agitation
- skin rashes (eruption of the skin), itching, hives, rash with blisters containing pus, pink/red blotchy
- rash which may form a ring, swelling of the skin particularly around the face
- abnormal liver function which may cause discomfort and tenderness in the upper abdomen, yellowing of the skin and whites of the eyes.
- low blood pressure
- increased sweating, fever

- An irregular heartbeat which may cause you to faint
- hepatitis.

If you get any 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

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Ireland

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ucerax Syrup

Keep out of the reach and sight of children.

Keep the bottle in the outer carton to protect from light.

Do not use Ucerax Syrup after the expiry date on the bottle and carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Return any medicine you no longer need to your pharmacist.

6. Further information

What Ucerax Syrup contains

The active substance in Ucerax Syrup is hydroxyzine dihydrochloride. The syrup contains 10 mg of hydroxyzine dihydrochloride in each 5 ml. The other ingredients are sucrose, ethanol (alcohol), sodium benzoate (E211), menthol, imitation hazelnut flavour and purified water.

What Ucerax Syrup looks like

Each bottle contains 200 ml of hazelnut flavoured syrup.

Marketing Authorisation Holder:

In the UK:

UCB Pharma Limited, 208 Bath Road, Slough, Berkshire, SL1 3WE, UK

In Ireland:

UCB Pharma (Ireland) Limited, United Drug House, Magna Drive, Magna Business Park, City West Road, Dublin 24, Ireland

Manufacturer:

NextPharma SAS, 17 route de Meulan, F-78520 Limay, France.

This leaflet was last updated in August 2015

If this leaflet is difficult to see or read or you would like it in a different format, please contact:

UCB Pharma Limited, 208 Bath Road, Slough, Berkshire, SL1 3WE, UK