

Patient Information Leaflet

Ucerax®

25 mg film-coated tablets
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 25 mg film-coated tablets are called Ucerax.

In this leaflet:

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

1. What Ucerax is for

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

Ucerax is used to treat:

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

2. Before you take Ucerax

Do not take Ucerax if:

- You are allergic to hydroxyzine hydrochloride or any of the other ingredients of Ucerax (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 before taking Ucerax 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 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 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 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 in your blood
- Monoamine oxidase inhibitors used for the treatment of depression
- Any other medicines including medicines obtained without a prescription.
- You are having allergy testing or a chest medical examination (asthma) in the next 5 days. Ucerax can affect the test results.

This medicine 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.

Taking Ucerax with food and drink

Do not drink alcohol whilst you are taking Ucerax

Pregnancy and breastfeeding

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

Driving and using machines

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

3. How to take Ucerax

Always take Ucerax 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.

Remember:

You may also need to break the tablets in half along the line down the middle. Your doctor or pharmacist will tell you how to do this.

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

In adults and children over 40 kg in weight, the maximum daily dose is 100 mg (4 tablets) per day in all indications.

Adults

For anxiety:

- The usual dose is ½ tablet at breakfast, ½ tablet at lunch and 1 tablet in the evening
- Your doctor may increase this to a maximum of 4 tablets taken three times a day.

For pruritis (itchiness of the skin):

- The usual dose is 1 tablet before going to bed
- Your doctor may increase this to 1 tablet three or four times a day
- Do not take more than 4 tablets for a single dose

- Do not take more than 4 tablets in one day.

Children

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

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

- The usual dose is 0.5 mg per kg of body weight twice a day
- Your doctor may increase this to a maximum of 1 mg per kg of body weight twice a day

The elderly

In the elderly, the maximum daily dose is 50 mg (2 tablets) per day.

- The usual starting dose is 25 mg (1 tablet) a day
- Your doctor will tell you how and when to take your tablets.

People with liver and kidney problems

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

If you take more Ucerax than you should

If you have used or taken too much Ucerax, 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 than you should you may feel sick or be sick, feel sleepy, confused, or have heart palpitations, 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

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 on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

Stop taking Ucerax 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.
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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
- fever
- increased sweating
- An irregular heartbeat which may cause you to faint
- hepatitis.

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.

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

Keep out of the reach and sight of children.

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

Store Ucerax tablets in the outer pack to protect from light.

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 contains

Each film-coated Tablet contains 25 mg hydroxyzine dihydrochloride

The other ingredients are lactose monohydrate, microcrystalline cellulose, magnesium stearate, anhydrous colloidal silica, titanium dioxide (E171), hydroxypropylmethylcellulose and macrogol 400.

What Ucerax looks like

The Ucerax film-coated tablets are white, oblong tablets with a score line on each side.

They come in blister strips in packs of 25, 30, 50 or 60 tablets. Not all pack sizes may be marketed.

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:

UCB Pharma SA, Chemin du Foriest, B-1420 Braine-l'Alleud, Belgium

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