

CETIHIS SYRUP 5MG/5ML

Cetirizine hydrochloride (5mg/5ml)

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What CETIHIS is used for

CETIHIS is used to treat adults and children aged 2 and over who have hay fever (seasonal allergic rhinitis), year-round allergies such as dust or pet allergies (perennial allergic rhinitis) and urticaria (swelling, redness and itchiness of the skin).

How CETIHIS works

CETIHIS contains an antihistamine called cetirizine which inhibits the effects of histamine produced during an allergic reaction. It also reduces the allergic reaction induced by specific allergens (substances that trigger allergic reactions).

Before you use CETIHIS

- When you must not use it

Do not take CETIHIS if:

- You are allergic (hypersensitive) to cetirizine dihydrochloride
- You are allergic (hypersensitive) to any of the other ingredients of CETIHIS
- You are breast-feeding
- You have severe kidney failure (Estimated Glomerular Filtration Rate) below 15 ml/min.
- You have problems of urinary retention.
- You have fructose intolerance.

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

- Before you start to use it

Check with your pharmacist before taking CETIHIS if:

- You have problems with your kidneys
- You have predisposition factors of urinary retention (eg: spinal cord

lesion, prostatic hyperplasia) as cetirizine increases the risk of urinary retention.

- You suffer from epilepsy or are at risk of convulsions.
- You want to use for children less than 2 years of age.

CETIHIS should be avoided in pregnant women. If you are pregnant or trying to become pregnant ask your pharmacist for advice before taking CETIHIS.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use CETIHIS

- How much to use

Adults

Take 10 ml oral solution once daily. A starting dose of 5 ml oral solution may be proposed if this leads to satisfactory control of the symptoms.

Children

Children aged from 2 to 6 years

Take 2.5 ml of oral solution in the morning and in the evening.

Children aged from 6 to 12 years

Take 5 ml of oral solution in the morning and in the evening.

Children over 12 years of age

Take 10 ml of oral solution once daily. The solution can be swallowed as such. Do not take more than 10 ml each day.

- When to use it

It is advisable to take the drug with little liquid during the evening meal since the symptoms for which the product is given usually appear during the night.

If you are affected by the side effects, the dose may be taken as 5 mg in the morning and 5 mg in the evening.

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking CETIHIS for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what should you do if you forget to use it.

If you miss a dose, take the next dose as soon as you remember, provided that you do not take more than the recommended dose in 24 hours. If it is almost time for your next dose, do not take the dose that you missed.

Do not take a double dose to make up for the missed one.

- If you use too much (Overdose)

If you accidentally take too much go and see your doctor straightaway.

Rarely, pruritus (intense itching) and/or urticaria may occur if you stop taking CETIHIS.

While you are using it

- Things you must do

- ✓ Take your medicine exactly as your doctor has prescribed.
- ✓ Inform all the doctors, dentists and pharmacists treating you that you are taking CETIHIS
- ✓ Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- ⊗ Do not stop taking the medicine unless advised by your doctor.
- ⊗ Do not take any new medicine without consulting your doctor.
- ⊗ Do not give CETIHIS to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

If you are due to have an allergy test, ask your doctor if you should stop taking CETIHIS for several days before testing. This medicine may affect your allergy test results.

Activities requiring mental alertness:

If CETIHIS make you feel dizzy, drowsy, agitated or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

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

The following side effect is very rare, but you must stop taking the medicine

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and speak to your doctor straight away if you notice these symptoms:

- A severe allergic reaction including rash, itchiness and fever, swollen throat, face, eyelids or lips. This reaction may start soon after you first take the medicine, or it might start later.

The following side effects have also been reported.

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

- Tiredness, feeling sleepy
- Pain in the abdomen
- Headache
- Dizziness
- Dry mouth
- Sore throat
- Nausea
- Cold-like symptoms of the nose (children only).
- Diarrhoea (children only)

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

- Itching (pruritus) and rash
- Tingling or numbness of the hands or feet (paraesthesia)
- Diarrhoea
- Feeling agitated.
- Feeling unusually weak (asthenia) or generally unwell (malaise)

Rare side effects (affects less than 1 in 1000 people)

- Hypersensitivity
- Fast heart beat (tachycardia)
- Oedema (generalised swelling due to water retention)
- Abnormal liver function test results (your doctor will know what to do)
- Convulsions
- Increased weight
- Aggression, confusion, depression, hallucination (hearing or seeing things), sleeplessness
- Urticaria (hives).

Very rare side effects (affects less than 1 in 10,000 people)

- Low blood platelets count (thrombocytopenia)
- Severe allergic reactions (anaphylactic shock)
- Blurred vision, difficulty focusing
- Eyes having uncontrolled circular movements (oculogyric crisis)

- Taste disturbance or loss of taste (dysgeusia)
- Fainting
- Bed wetting, pain and/or difficulty passing water
- Tremor, tics (uncontrolled body movements)
- Uncontrollable movements (dyskinesia)
- Uncontrolled muscle spasm (dystonia)
- Serious allergic reaction which causes swelling of the face or throat (angioedema)
- Small patches of swelling and redness of the skin, which may blister (fixed drug eruption)

Not known side effects

- Increased appetite
- Nightmare
- Spinning sensation (vertigo)
- Inflammation of the liver (hepatitis)
- Rash with blisters containing pus
- Joint pain (arthralgia, myalgia)
- Urinary retention (difficulty passing urine)
- Intense itching (pruritus) upon discontinuation

Some cases of memory loss and/or impairment have also been reported.

In very rare cases people have thought about committing suicide and if you feel this way then stop taking CETIHIS and see your doctor.

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of CETIHIS

- Storage

Keep medicine out of reach of children.

Store at temperature of not more than 30°C

- Disposal

Medicine should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines

no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Clear, colorless syrup with banana-grape flavor.

- Ingredients

Active ingredient:

Cetirizine dihydrochloride.

Inactive ingredients:

Sucrose, Methyparaben, Propylparaben, Citric acid, Sodium citrate, Sodium chloride, Glycerin, Propylene glycol, Banana flavor, Grape flavor and Purified water.

MAL number:

MAL09051539AZ

Manufacturer

UNISON LABORATORIES CO., LTD.
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Product Registration Holder

Medispec (M) Sdn Bhd
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