

CETIHIS SYRUP

Cetirizine hydrochloride (5mg/5ml)

Consumer Medication Information Leaflet (RiMUP)

What is in this leaflet

1. What CETIHIS is used for
2. How CETIHIS works
3. Before you use CETIHIS
4. How to use CETIHIS
5. While you are using it
6. Side effects
7. Storage and disposal of CETIHIS
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

What CETIHIS is used for

Symptomatic treatment of seasonal rhinitis (inflammation of the mucous membrane inside the nose), perennial allergic rhinitis (year-round allergy) and urticaria (hives) of allergic origin.

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

- ⊗ If you are allergic (hypersensitive) to Cetirizine or to any of the other ingredients of CETIHIS.
- ⊗ If you ever had a bad reaction to any other antihistamine containing products.
- ⊗ If your child has kidney or liver disease.
- ⊗ If you are Pregnant and breast-feeding
 - ⇒ You should avoid using CETIHIS if you are pregnant, especially during the first trimester. CETIHIS may be used only if the doctor decides that the anticipated benefit of the treatment outweighs the potential risks to the fetus.
 - If you are planning to become pregnant or think that you may be pregnant, speak to your doctor to know if CETIHIS is suitable for you.
 - ⇒ Do not take CETIHIS if you are breast-feeding or planning to breast-feed, as it has been reported that Cetirizine may pass into the mother's milk.

Do not use this medicine if any of the above applies to you. If you are not sure, get advice from your doctor or pharmacist before taking CETIHIS.

- Before you start to use it

Activities requiring mental alertness:

Occurrence of somnolence (sleepiness or unusual drowsiness) has been reported in some patients taking Cetirizine. Thus, due caution should therefore be exercised when driving a car or operating potentially dangerous machinery.

- Taking other medicines

Please inform your doctor or pharmacist if you are using or have recently used any other medicines. This includes medicines that you buy without prescription and herbal medicines. This is because CETIHIS can affect the way some medicines work. Also some other medicines can affect the way CETIHIS works.

In particular, tell your doctor or pharmacist if you are using any sedatives (drugs that reduce or relieve anxiety, stress, irritability or excitement). CETIHIS should be used with caution if you have taken or is currently using sedatives.

How to use CETIHIS

- How much to use

Oral

Adult

10 mg once daily

Children

> 6 years:

10 mg daily, either 5 mg twice daily or 10 mg once daily

3 – 6 years:

5 mg daily, either 2.5 mg twice daily or 5 mg once daily

Patients with kidney problem

Dosage should be reduced to ½ the daily dose.

Oral solution: 10 mL solution = 10 mg or
5 mL solution = 5 mg or
2.5 mL solution = 2.5 mg

As with any drug, if you notice any undesirable effect, discontinue using and consult your doctor.

Follow carefully all directions given to you by your doctor and pharmacist. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- 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)

The most likely sign of a possible overdose includes drowsiness that might occur from taking 50 mg of Cetirizine as a single dose. In children agitation can be a symptom of overdosage.

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else have accidentally taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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

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.

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Side effects

As with all drugs, CETIHIS is likely to have undesirable effects, although not everybody gets them.

- Headache
- Dizziness
- Drowsiness
- Agitation
- Dry mouth
- Gastrointestinal discomfort
- Hypersensitivity

If any of the side effects happens, or if you notice any undesirable effects which have not been mentioned here, discontinue using this medication and consult your doctor / pharmacist or go to the nearest hospital immediately.

You may report any side effects or adverse drug reactions directly to the **National Centre for Adverse Drug Reaction Monitoring** by calling *Tel: 03-78835550*, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of CETIHIS

- *Storage*

Keep medicine out of reach of children.

Store at temperature of not more than 30°C

- *Disposal*

Shelf – life: Three (3) years

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: MAL09051539A

Manufacturer

UNISON LABORATORIES CO., LTD.

39 Moo 4, Klong Udomcholjorn, Muang Chachoengsao, Chachoengsao 24000 Thailand

Product Registration Holder

MEDISPEC (M) SDN. BHD

55 & 57 Lorong Sempadan 2, (Off Boundary) 11400 Ayer Itam, Penang, Malaysia

Date of Revision

13/03/2015

Serial number

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