

MEDIZINE SYRUP 5MG/5ML

Cetirizine hydrochloride (5mg/5ml)

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What Medizine Syrup is used for

Medizine Syrup 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 Medizine Syrup works

The active ingredient this medicine is cetirizine. It belongs to a group of medicines called antihistamines. It works by blocking a certain natural substance (histamine) that your body makes during an allergic reaction.

Before you use Medizine Syrup

- When you must not use it

Do not use Medizine Syrup if you:

- are hypersensitive to cetirizine, hydroxyzine, piperazine or any other ingredients listed at the end of the leaflet.
- have severe kidney failure (creatinine clearance less than 10ml/min).

Children

Medizine Syrup is not recommended to be used for children under 2 years of age.

- Before you start to use it

Tell your doctor before taking this medicine if you have:

- moderate or severe kidney problem.
- have difficulty in urination.
- fits.
- convulsion.

Pregnancy and breastfeeding

You should check with your doctor if you are or think you may be pregnant, planning to become pregnant or if you are breastfeeding.

It is not recommended for pregnant women and nursing mothers unless the expected benefit outweighs any potential risks.

There is inadequate evidence of safety in human pregnancy or fertility. Safety during pregnancy has not been established. Caution should be taken when breastfeeding as cetirizine found excreted in breast milk.

- Taking other medicines

There are no known interactions with other drugs. Nevertheless, cetirizine should be used with caution if concomitant administration with alcohol or other central nervous system (CNS) depressants are also being taken.

How to use Medizine Syrup

- How much to use

You should take Medizine Syrup exactly as advised by your doctor or pharmacist. The amount you take each day will depend on your condition. Do not take more or less than what your doctor prescribes.

Oral administration.

Adults: An initial dose 5mg depending on the satisfactory of the symptoms or else 10mg once daily.

Children 12 years of age above: 10mg, once daily.

Children from 6- 12 years of age: 5mg, twice daily.

Children from 2- 6 years of age: 2.5mg, twice daily.

Recommended dose for adult with kidney and liver problem

Stage	Creatinine level (ml/min)	Dose
Normal	≥80	10 mg once daily
Mild	50-79	10 mg once daily
Moderate	30-49	5 mg once daily
Severe	< 30	5 mg once every 2 days
End-stage renal disease –Adults undergoing dialysis	< 10	Not recommended

In children with kidney problem, the dose will be adjusted based on kidney clearance, age and body weight.

- When to use it

Use Medizine Syrup when needed and according to doctor's prescription.

- How long to use it

It is important to take Medizine Syrup as long as your doctor prescribes.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

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

Symptom of over dosage include central nervous system (CNS) depressants, confusion, diarrhea, dizziness, fatigue, headache, malaise, dilated pupils, restlessness, sedation, sleepiness progressing to coma, stupor, rapid heart rate, shaking and have difficulty in urination.

While you are using it

- Things you must do

- Take your medications as directed by your doctor.
- Inform all doctors, dentists and pharmacists who treat you that you are using Medizine Syrup.
- 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 medicines without consulting your doctor.
- Do not give Medizine Syrup to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

This medicine may affect your ability to drive or use machines. If this medicine makes you feel drowsy, do not drive or use machines and contact your doctor immediately.

Avoid consuming alcohol.

Side Effects

Like all medicines, Medizine Syrup can cause side effects, although not everybody gets them. The following side effect is very rare, but you must stop taking the medicine 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:

- 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 :

- 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 :

- Low blood platelets count (thrombocytopenia)
- Severe allergic reactions (anaphylactic shock)
- Blurred vision, difficulty focusing

- Eyes having uncontrolled circular movements (oculogyration)
- 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)
- 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 Medizine 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 npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Medizine Syrup*- Storage*

Store at or below 30 ° C. Protect from light.

- Disposal

Medicines 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*

A clear, colourless syrup with banana flavour.

- Ingredient(s)

- Active Ingredient

- Cetirizine HCl

- Inactive Ingredients

- Citric Acid
- Saccharin Sodium
- Sodium Benzoate
- Glycerine
- Banana Flavour
- Coarse Sugar
- Deionised water

- MAL number

MAL

Manufacturer

Sunward Pharmaceutical Sdn. Bhd.
No. 9,11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

Product Registration Holder

World Medicare Supplies Sdn.Bhd
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