

ALATROL SYRUP 5MG/5ML

Cetirizine Hydrochloride (5mg/5ml)

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What Alatrol Syrup is used for

Alatrol Syrup is used for seasonal symptomatic treatment. It can be used to treat:

- Rhinitis (irritation and inflammation of the mucous membrane inside the nose).
- Perennial allergic rhinitis (symptoms year-round due to indoor allergens from pets, mold, dust mites and cockroach residue).
- Urticaria (itchy areas of skin) of allergic origin.

How Alatrol Syrup works

Alatrol Syrup 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 Alatrol Syrup

- When you must not use it

Do not take this medicine if:

- you are allergic to any of its ingredients.
- you are a nursing mother.
- you have severe renal impairment

Pregnancy and lactation

Do not take Alatrol Syrup if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Alatrol Syrup if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Tell your doctor if:

- If you are allergic to any medicines, food and dyes.
- If you are taking any other medicines (including those not prescribed by your doctor).
- If you are pregnant or nursing babies.

- 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 as it may interact with your Alatrol Syrup:

- Alcohol or other central nervous system (CNS) depressants.

How to use Alatrol Syrup

- How much to use

Adult: 10 mg (20 drops or 10 ml oral solution or 1 tablet) once daily. A 5 mg starting dose (10 drops or 5 ml of oral solution or half of the tablet) may be proposed if this leads to satisfactory control of the symptoms.

Children:

Children aged from 2 to 6 years 2.5 mg (5 drops or 2.5 ml of oral solution bid) twice daily.

Children aged from 6 to 12 years 5 mg (10 drops or 5 ml of oral solution or half of the tablet) twice daily.

Children over 12 years of age 10 mg (20 drops or 10 ml of oral solution or 1 tablet) once daily.

Elderly

Data do not suggest that the dose needs to be reduced in elderly subjects provided that the renal function is normal.

Patients with renal impairment, the dose intervals must be individualised according to renal function.

Follow all directions given to you by your doctor and pharmacist carefully. 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

Use as directed by your doctor or pharmacist.

- How long to use it

Use this medicine for the duration that your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do 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 or anyone else may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause restlessness and irritability, followed by drowsiness. Should overdose occur, treatment should be symptomatic or supportive, taking into account any concomitantly ingested medications.

In case of massive overdose, gastric lavage should be performed as soon as possible. Usual supportive measures should be provided and routine observation carried out regularly.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Alatrol Syrup.

Tell your doctor immediately if you become pregnant while using this medication. *(if applicable)*

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

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Do not give Alatrol Syrup to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

- Avoid use with alcohol.
- Caution when you have problems with difficulty in urination.
- Caution if you have epilepsy.
- Special precaution should be given to children below 2 years old.

Driving and using machines

This medicine may affect your ability to drive or use machines. If this medicine makes you feel *sick, dizzy or tired, or give you a headache*, do not drive or use machines and contact your doctor immediately.

Side effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Cetirizine at recommended dosage has minor undesirable effects such as drowsiness, fatigue, dizziness, headache, difficulty in urination, eyes disorders, dry mouth, and abnormal liver function with increased liver enzymes which resolve after stopping cetirizine treatment.

Below are side effects reported which estimated by frequency. Frequencies are defined as follows: Very common; common; uncommon; rare; very rare, not known.

Blood and lymphatic disorders

Very rare: thrombocytopenia (deficiency of platelets in the blood)

Immune system disorders

Rare: hypersensitivity
Very rare: anaphylactic shock

Metabolism and nutrition disorders

Not known: increased appetite

Psychiatric disorders

Uncommon: agitation
Rare: aggression, confusion, depression, hallucination, insomnia
Very rare: tics (unintentional, fast and repetitive muscle movements)
Not known: suicidal ideation

Nervous system disorders

Uncommon: paraesthesia (abnormal sensation, typically tingling or pricking)
Rare: convulsions
Very rare: dysgeusia (foul, salty, rancid, or metallic taste sensation will persist in the mouth), syncope (temporary loss of consciousness), tremor, dystonia (movement disorder in which a person's muscles contract uncontrollably), dyskinesia (involuntary muscle movements)
Not known: amnesia (loss of memories), memory impairment

Eye disorders

Very rare: accommodation disorder, blurred vision, oculogyration (movement of the eyeball)

Ear and labyrinth disorders

Not known: vertigo

Cardiac disorders

Rare: tachycardia (increased heart rate)

Gastro-intestinal disorders

Uncommon: diarrhoea

Hepatobiliary disorders

Rare: hepatic function abnormal (increased transaminases, alkaline phosphatase, γ -GT and bilirubin)

Skin and subcutaneous tissue disorders

Uncommon: pruritus, rash
Rare: urticaria
Very rare: angioneurotic oedema, fixed drug eruption

Renal and urinary disorders

Very rare: difficulty urination, involuntary urination
Not known: urinary retention

General disorders and administration site conditions

Uncommon: asthenia (weakness), malaise
Rare: oedema

Investigations

Rare: weight increased

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 Alatrol Syrup

- Storage

Keep out of the reach and sight of children.

Store below 30 °C.

- 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 light yellow color lemon flavored clear liquid.

- Ingredients

- Active ingredient(s)
Cetirizine hydrochloride

- Inactive ingredients
Glycerol, Liquid Sorbitol (Non-crystallising), Saccharin Sodium, Anhydrous Citric Acid Sodium Citrate, Menthol, Propylene Glycol, Polyoxyl-40 Hydrogenated Castor Oil, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate, Lemon Tetraome 987317, D & C Yellow No. 10, Purified Water

- MAL number:

MAL17035030AZ

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Cetirizine Hydrochloride (5mg/5ml)

Manufacturer

SQUARE PHARMACEUTICALS PLC.
Square Road, Salgaria, Pabna 6600
Bangladesh

Product Registration Holder

Medispec (M) Sdn Bhd
B-1-07, Jalan SS 25/22,
Taman Mayang,
47301 Petaling Jaya, Selangor,
Malaysia.

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