

AVICET SYRUP 0.1% W/V

Cetirizine Hydrochloride 1mg /1 mL

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1. What Avicet Syrup is used for

Avicet 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).

2. How Avicet Syrup works

The active ingredient 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.

3. Before you use Avicet Syrup

- When you must not use it

Do not use 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 15ml/min).
- are breastfeeding

Children

It is not recommended to use for children under 2 years of age.

- Before you start to use it

Check with your doctor before taking this medicine if you have:

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

4. How to use Avicet Syrup

- How much to use

You should take this medicine 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.

Children from 2-6 years of age: 2.5 mg (2.5 ml of oral solution) twice daily.

Children from 6-12 years of age: 5 mg (5 ml of oral solution) twice daily.

Children 12 years of age and above: 10 mg (10 ml of oral solution) once daily.

Adults: 10 mg (10 ml oral solution) once daily. A 5 mg starting dose (5 ml of oral solution) may be proposed if this leads to satisfactory control of the symptoms.

The solution can be swallowed as such. Do not take more than 10ml each day.

- When to use it

Use when needed and according to doctor's prescription.

- How long to use it

It is important to take this medicine 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

Symptoms 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.

5. While you are using Avicet Syrup

- 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 this medicine
- 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 this medicine 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

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not drive or use machines and contact your doctor immediately.
Avoid consuming alcohol.

6.Side Effects

Like all medicines which 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 (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), sleepless-ness

- Urticaria (hives).

Very rare side effects (affects less than 1 in 10000 people):

- 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 this medicine 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)].

7.Storage and disposal

- Storage

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.

8.Product Description

- What it looks like

It is a clear and colourless syrup with banana flavour.

- Ingredients

Active ingredient:

Cetirizine Hydrochloride

Inactive ingredients:

Purified water, sorbitol, Banana flavour, Methyl paraben, Saccharin sodium, Glycerine, Sodium acetate, glacial acetic acid

- MAL Number

MAL24056088AZC

9. Manufacturer

AV Manufacturing Sdn Bhd (667760-v)

Lot 10621 (PT16700), Jalan Permata 2, Arab Malaysian Industrial Park 71800 Nilai, Negeri Sembilan.

10. Product Registration Holder

Advance Pharma Sdn Bhd (539885-W)

28, Jalan BP6/6, Bandar Bukit Puchong, 47120 Puchong, Selangor.

11.Date of revision

30 Aug 2024

12.Serial Number

NPRA(R2) 23/153