ADEZIO FC TABLET/ ORAL SOLUTION

Cetirizine Hydrochloride (10mg, 1mg/ml)

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What is Adezio used for

- It is used to relieve perennial (throughout the year) and seasonal allergic symptoms such as sneezing, itchy, runny and blocked nose, and itchy, red and watery eyes in adult and children over 1 year old.
- It is also used to treat uncomplicated skin manifestations of chronic idiopathic urticaria (occurrence of red, raised itchy rash with no obvious cause) in adults and children over 1 year of age.

How Adezio works

Cetirizine is the antihistamine, which works by blocking the action of histamine, a substance in the body that causes allergic symptoms. Histamine is a chemical substance that released in the body as part of an allergic reaction.

Before you use Adezio

When you must not use it

Do not use Adezio if you are allergic to any ingredients in this medicine.

Before you start to use it

Tell your doctor or pharmacist before using Adezio if you:

- are pregnant or plan to get pregnant. Adezio should not be used during the first trimester of pregnancy.
- are breast-feeding or plan to start breast-feeding. Cetirizine has been reported to be excreted in human breast milk. Therefore, the use of cetirizine in nursing mothers is not recommended.
- have kidney or liver problems.
- the safety and effectiveness of cetirizine in children under age of 1 year have not been established.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes any medicines which you have bought without a prescription.

Caution should be taken when orther central nervous system (CNS) depressants or alcohol is taken concurrently.

How to use Adezio

How much to use

Adezio FC Tablet

Adults and children 6 years and above ½ tablet or 1 tablet once daily

Adezio Oral Solution

Adults and children 6 years and above 1 or 2 teaspoons once daily.

Children 1 to 5 years

½ or 1 teaspoon once daily, Or ½ teaspoon twice daily

When to use it

Can be taken with or without food. Follow the prescription from your doctor or pharmacist.

How long to use it

Follow the prescription from your doctor or pharmacist. Ask your doctor or pharmacist before prolonged use of this medicine.

<u>If you forget to use it</u>

Use it as soon as you remember, unless it is nearly time for your next dose, skip the missed dose. Then go on as before. Never double up on the next dose to make up for the one missed.

If you use too much (overdose)

Symptoms of overdose include sleepiness, restlessness, irritability and drowsiness.

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.

While you are using Adezio

Things you must do

- Always wash your hand before handle the medicine.
- Take the medicine at the same time each day.
- For oral solution, sip and swallow the medicine slowly, preferably taken without dilution.

Things you must not do

- Do not chew the tablets. Swallow it with water.
- Do not use this medicine by yourself without prescription from your doctor or pharmacist.
- Do not take any new medicines without consulting your doctor.
- Do not give Adezio to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

The occurrence of sleepiness has been reported in some patients taking cetirizine in clinical trials. Caution should therefore be exercised when driving a car or operating potentially dangerous machinery.

Side effects

- Drowsiness.
- Dizziness.
- Agitation.Dry mouth.
- Gastrointestinal discomfort
- Hypersensitivity reactions

Seek immediate medical attention if you experience any side effects or allergic reactions. Other side effects not listed above may also occur in some people.

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 Adezio

St<u>orage</u>

Store in a cool place, below 30 °C. Keep out of the reach of the children. Do not use this medicine after expiry date.

<u>Disposal</u>

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

How it looks like

Adezio FC Tablet

White colour, oblong shape, normal convex film-coated tablet with break line and "XS" logo.

ADEZIO FC TABLET/ ORAL SOLUTION

Cetirizine Hydrochloride (10mg, 1mg/ml)

Adezio Oral Solution

Clear, colorless oral solution with fruity flavor.

Ingredients

Adezio FC Tablet

Active Ingredient

Cetirizine Hydrochloride.

Inactive ingredients

Colloidal Silicon Dioxide, Magnesium Stearate, Starch, Microcrystalline Cellulose, Cellulose Lactose Compound Mix, HPMC Compound Mix, Methanol, Purified Water.

Adezio Oral Solution

Active Ingredient

Cetirizine Hydrochloride.

Inactive ingredients

Propylene Glycol, Glycerin, Cellogen F-SH, Methyl Hydroxybenzoates, Propyl Hydroxybenzoates, Saccharin Sodium, Sodium Acetate Anhydrous, Glacial Acetic Acid, Lychee Flavour, Purified Water.

MAL Number

Adezio FC Tablet: MAL20020358AZ Adezio Oral Solution: MAL20021146AZ

Manufacturer and Product Registration Holder

Xepa-Soul Pattinson (Malaysia) Sdn Bhd 1-5 Cheng Industrial Estate, 75250 Melaka, Malaysia.

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