



**PATIENT INFORMATION LEAFLET:
INFORMATION FOR THE USER**

CITRAMINE TABLETS/SYRUP

Active substance(s)

Citramine Tablets.

Each tablet contains Cetirizine hydrochloride BP 10 mg.

Citramine Syrup:

Each 5ml contains Cetirizine hydrochloride BP 5mg

Read this entire leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

This leaflet Contains:

1. What Citramine Tablets/Syrup is and what it is used for
2. What you should know before you take Citramine Tablets/Syrup
3. How to take Citramine Tablets/Syrup
4. Possible side effects
5. How to store Citramine Tablets/Syrup
6. Further information

1. WHAT CITRAMINE TABLETS/SYRUP IS AND WHAT IT IS USED FOR

Citramine is Antihistamine medication. It is indicated for symptomatic relief of hypersensitivity reactions including rhinitis and chronic urticaria. Seasonal and perennial allergic rhinitis with symptoms such as sneezing, rhinorrhoea, nasal pruritis, tearing and redness of the eye caused by allergens such as grass, tree pollens, dust, mould etc, can be treated with Citramine. It is also indicated for the treatment of the uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 2 years and above.

2. WHAT YOU SHOULD KNOW BEFORE YOU TAKE CITRAMINE TABLETS/SYRUP

Do not take Citramine Tablets/Syrup

- if you are allergic (hypersensitive) to Cetirizine Hydrochloride or any of the other ingredients of Citramine Tablets/Syrup
- if you are allergic to hydroxyzine
- if you have hereditary problems of galactose intolerance, Lapp lactose deficiency or glucose galactose malabsorption
- if you have severe kidney disease (severe renal failure with creatine clearance below 10/ml/min)

Take special care with Citramine Tablets/Syrup

- if you are an epileptic patient or a patient at risk of convulsions (fit)
- If you were diagnosed with kidney problem before. Reduced dosage is recommended for patients with renal impairment
- If you have spinal cord lesion or enlargement of the prostate or any predisposing factors for urinary retention.
- When you require an allergy test, you should stop taking Citramine three days before you have the test. Citramine Tablets/Syrup can affect the results of allergy skin tests

Long term treatment with cetirizine can increase the risk of tooth decay due to mouth dryness. Appropriate oral hygiene is important in long term use.

Taking Citramine Tablets/Syrup with other medicines

Please tell your doctor, health care provider or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Citramine may enhance the sedative effects of central nervous system depressants including alcohol, barbiturates, hypnotics, opioid analgesic, anxiolytic sedatives and neuroleptics.

Taking Citramine Tablets/Syrup with food and drink

Citramine Tablets/Syrup can be taken with or without food. Be careful when drinking alcohol with Citramine Tablets/Syrup

Pregnancy and Breastfeeding

Ask your doctor, health care provider or pharmacist for advice before taking this medicine if you are pregnant or breast feeding, think you might be pregnant or are planning to become pregnant. You should not take Citramine during breast feeding because cetirizine passes into the breast milk, ask your doctor, health care provider or pharmacist for advice before. Accidental use of the drug by a pregnant woman should not produce any harmful effects on the foetus. Nevertheless, the administration of the medicine should be discontinued.

Driving and Using Machines

Clinical studies did not give any evidence that Cetirizine influence ability to drive or use machinery at recommended level. You are however asked to closely observe your response to the medicine regarding alertness and impaired attention. Do not use machinery if the medicine makes you fill drowsy.

Important information about some of the ingredients in Citramine Syrup

The Syrup contains sorbitol. If you are told you have intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE CITRAMINE TABLETS/SYRUP

Always take **Citramine Tablets/Syrup** exactly as your doctor or health care provider has told you. You should check with your doctor, health care provider or pharmacist if you are not sure. The usual dose is:

Adults and children 12 years and above: Given by mouth as a single dose of 10 mg daily or 5mg twice daily. In the case of renal impairment, a single dose of 5mg once daily is recommended.

Children 6-11 years: 5mg as a single dose or divided dose depending on the severity of symptoms

Children 2 -5 years. The recommended dose is 2.5mg daily as a single dose. The dosage in this group can be increased to a maximum of 5mg per day given as a 1 teaspoonful (5ml) or half teaspoon (2.5ml) every 12 hours depending on the severity of symptoms and patient renal response.

Not recommended for children under 2 years of age

If you take more Citramine Tablets/Syrup than you should:

If you have accidentally taken more than the recommended dose, contact your nearest hospital casualty department or tell your doctor or pharmacist immediately. Remember to take the pack and any remaining medicine with you.

The most common signs of overdose include feeling unwell, headache, confused, restlessness, shaky, dizziness, sleepy. You may also notice difficulty urinating, rapid heartbeat, dilated pupils, blurred vision, itching and even diarrhea. In adults severe over dosage may lead to cardiovascular collapse.

In severe over dosage the stomach should be emptied. Activated charcoal may also be given, as well as saline laxatives. Convulsion may be controlled with diazepam. Vasopressors such as noradrenaline may be used. But not adrenaline as it can lower the blood pressure further.

If you forget to take Citramine Tablets/Syrup

Do not take a double dose to make up for a forgotten tablet/syrup. If you forgot to take your medicine, take it as soon as you remember and then wait 24 hours before you take the next dose.

If you stop taking Citramine Tablets/Syrup

If you have any further questions on the use of this product, ask your doctor, health care provider or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist:

- Drowsiness, fatigue, dry mouth, nausea (feeling sick), diarrhea, dizziness, headache, sore or inflamed throat, swelling and irritation of the lining of the nose (runny nose), restlessness, abdominal pain
- Symptoms of serious side effects include; sudden wheeziness, difficulty in breathing, sudden signs of an allergic reaction such as developing a rash,

swelling of the eyelids, face, lips or throat. Loss of consciousness, convulsions or fit, bruising or bleeding more easily than normal, weight loss, a worsening cough, fatigue, rapid heartbeats, involuntary eye movement, oedema (swell of the feet or ankles), hives, hallucinations, difficulty in sleeping.

In very rare cases people have had suicidal thoughts when taking medication containing cetirizine hydrochloride. If you experience these, stop taking the medicine and see your doctor. Changes in liver function test may indicate the possibility of liver damage.

5. HOW TO STORE CETIRIZINE

Keep out of the reach and sight of children.

Do not store above 30 °C, Store in the original container and carton box

Do not use Citramine after the expiry date which is stated on the label of the bottle or on carton box or stated on the aluminium blister foil of the tablet. The expiry date refers to the last day of that month.

Do not use Citramine if you notice visible signs of deterioration

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.

6. FURTHER INFORMATION

What Citramine Tablets/Syrup contains

The active substances in both Citramine Tablets and Citramine Syrup is Cetirizine Hydrochloride

The other ingredients are:

Tablets: Dicalcium Phosphate granules, lactose, Micro Crystalline Cellulose Avicel, Magnesium Stearate, Talc, Cab-O-Sil.

Syrup: Sorbitol 70%, Sodium Citrate, Propylene glycol, Methyl Paraben, Propyl paraben, Saccharin Sodium, Flavour raspberry, Citric Acid, Sugar

What Citramine looks like and contents of the pack

Tablet: white oval Shaped tablet with 'LETAP' on one side and break line on the other side.

Blister Pack of PVC and Aluminium foil Containing 10 tablets (Primary Packaging). Blister Pack of 10 X 10 Tablets in a Carton Box (Secondary Packaging)

Syrup: Clear or almost clear, colourless solution with orange flavor available in 60 mL amber plastic bottle with white P.P aluminium cap in a skillet/carton box.

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