

GLENCET M FILM-COATED TABLETS

Montelukast and Levocetirizine Dihydrochloride Tablets (10mg + 5mg)

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What Glencet M is used for

Glencet M contains the active ingredients Montelukast sodium and Levocetirizine dihydrochloride. Glencet M is used for the treatment of relief of symptoms associated with seasonal allergic rhinitis..

How Glencet M works

Montelukast is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs and also cause allergy symptoms. By blocking leukotrienes, montelukast improves seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis). Levocetirizine is a potent and selective antihistamine which blocks the action of substance called histamine which is produced in the body during an allergic reaction.

Before you take Glencet M

-When you must not use it

a) If you are allergic to montelukast, levocetirizine dihydrochloride, cetirizine, hydroxyzine or any of the other ingredients of this medicine.

- b) if you have a severe impairment of kidney function (severe renal failure with creatinine clearance below 10 ml/min)
- c) if you have rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

- Before you start to use it

Talk to your doctor or pharmacist before taking Glencet M

Children and adolescents

The use of Glencet M is not recommended in children less than 18 years since this product has not been studied.

-Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines including those obtained without a prescription.

Tell your doctor if you are taking the following medicines before starting Glencet M:

- phenobarbital (used for treatment of epilepsy)
- phenytoin (used for treatment of epilepsy)
- rifampicin (used to treat tuberculosis and some other infections)
- gemfibrozil (used for treatment of high lipid/fat level in blood)

How to take Glencet M

-How much to use

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- You should take only one tablet of Glencet M once a day as prescribed by your doctor.

For adults (≥18 years of age):

The recommended dose is one tablet to be taken daily in the evening.

If you are taking Glencet M, be sure that you do not take any other products that contain the same active ingredients, montelukast and levocetirizine.

Use in children and adolescents (<18 years)

This medicinal product is not recommended in children and adolescents (<18 years).

Special dosage instructions for specific populations:

Kidney and liver impairment:

Patients who have severe impairment of kidney function must not take Glencet M. No dose adjustment is needed in patients with mild kidney impairment (creatinine clearance >79 ml/min). For patients with moderate to severe kidney impairment (creatinine clearance <79 ml/min - >10ml/min), this product is to be used with caution and under strict medical supervision.

No dosage adjustment is needed in patients with impaired liver function.

-When to use it

This medicine is for oral use. Glencet M should be swallowed whole with water and may be taken with or without food.

-How long to use it

The duration of use depends on the type, duration and course of your complaints and is determined by your physician.

-If you forget to use it

Try to take Glencet M as prescribed.

If you forget a dose, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose and go back to your regular schedule.

Do not take a double dose (two doses

on the same day) to make up for a forgotten dose.

-If you use too much (overdose)
Contact your doctor immediately for advice.

There were no side effects reported in the majority of overdose reports. The most frequently occurring symptoms reported with overdose in adults or children and adolescents included abdominal pain, sleepiness, thirst, headache, vomiting, and hyperactivity. If you take more Glencet M than you should, sleepiness (somnia) can occur in adults. Children may initially show excitement and restlessness followed by sleepiness(somnia)

While you are using Glencet M

-Things to be careful of

If you are likely to be unable to empty your bladder (with conditions such as spinal cord injury or enlarged prostate), please ask your doctor for advice.

If you suffer from or are at risk of seizure/fits, please ask your doctor for advice as use of levocetirizine may cause seizure/ fits aggravation.

If you are scheduled for allergy testing, ask your doctor if you should stop taking levocetirizine for several days before testing. This medicine may affect your allergy test results.

Patients should be aware of any behavior and mood-related symptoms (such as agitation including aggressive behavior or hostility, depression, obsessive-compulsive symptoms) associated with the use of montelukast. If patient develop such symptoms while taking montelukast, please consult the doctor.

Side Effects

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

In clinical study with Glencet M conducted in patients with seasonal allergic rhinitis, all reported side effects were considered to be unrelated to treatment except for one adverse event (1.1%) of hypersomnia/excessive sleepiness. The side effects reported during conduct of the study were mild to moderate.

Montelukast:

Common ($\geq 1/100$, to $< 1/10$):

- Abdominal pain
- Headache

Uncommon ($\geq 1/1,000$, to $< 1/100$):

- allergic reactions including swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing
- behaviour and mood related changes: agitation including aggressive behaviour or hostility, depression
- seizure/fit

Levocetirizine:

Common ($\geq 1/100$, to $< 1/10$):

Dry mouth,
headache,
tiredness
sleepiness(somnia) /
drowsiness

Uncommon ($\geq 1/1,000$, to $< 1/100$):

Exhaustion
abdominal pain

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 Glencet M

-Storage

Store below 30°C. Protect from light and moisture.

-Disposal

Any used medicinal product or waste material should be disposed of in accordance with local requirements

Product Description

-What it looks like

Yellow, round, biconvex, film coated tablets plain on both sides. Pack size of 14 tablets: A labeled sealed HDPE container fitted with cap containing "1G silica gel canister" containing 14 tablets.

-Ingredients

Active ingredient
Montelukast Sodium and
Levocetirizine Dihydrochloride

Inactive ingredients

Microcrystalline cellulose, lactose monohydrate, Anhydrous dibasic calcium phosphate, croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, Opadry yellow (13B52204)

-MAL number:

Manufacturer and Product Registration Holder

Manufacturer:

Glenmark Pharmaceuticals
Limited
Unit I Village Kishanpura, Baddi
Nalagarh Road, Tehsil Baddi,
District: Solan(H.P) 173205 India

Product Registration Holder

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