



Glemont-IR 10
(Montelukast Tablets 10 mg)

1.3.2 Patient Information Leaflet

Enclosed

INFORMATION FOR THE PATIENT
Glemont (Montelukast) 10 mg film-coated tablets

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have more questions, ask your doctor 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 or pharmacist.

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1. What Glemont is and what it is used for

Glemont 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, Glemont improves asthma symptoms, helps control asthma and improves seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis).

Your doctor has prescribed Glemont to treat asthma, preventing your asthma symptoms during the day and night.

- Glemont is used for the treatment of patients who are not adequately controlled on their medication and need additional therapy.
- Glemont also helps prevent the narrowing of airways triggered by exercise.
- In those asthmatic patients in whom Glemont is indicated in asthma, Glemont can also provide symptomatic relief of seasonal allergic rhinitis.

Your doctor will determine how Glemont should be used depending on the symptoms and severity of your asthma.

What is asthma?

Asthma is a long-term disease.

Asthma includes:

- difficulty breathing because of narrowed airways. This narrowing of airways worsens and improves in response to various conditions. sensitive airways that react to many things, such as cigarette smoke, pollen, cold air, or exercise.
- swelling (inflammation) in the lining of the airways.

Symptoms of asthma include: Coughing, wheezing, and chest tightness.

What are seasonal allergies?

Seasonal allergies (also known as hay fever or seasonal allergic rhinitis) are an allergic response often caused by airborne pollens from trees, grasses and weeds. The symptoms of seasonal allergies typically may include: stuffy, runny, itchy nose; sneezing; watery, swollen, red, itchy eyes.

2. Before you take Glemont

Tell your doctor about any medical problems or allergies you have now or have had.

Do not take Glemont if you

- are allergic (hypersensitive) to montelukast or any of the other ingredients of Glemont (see 6. Further information).

Take special care with Glemont

- If your asthma or breathing gets worse, tell your doctor immediately.
- Oral Glemont is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you. Always have your inhaled rescue medicine for asthma attacks with you.
- It is important that you or your child take all asthma medications prescribed by your doctor. Glemont should not be substituted for other asthma medications your doctor has prescribed for you.
- Any patient on anti-asthma medicines should be aware that if you develop a combination of symptoms such as a flu-like illness, pins and needles or numbness of arms or legs, worsening of pulmonary symptoms, and/or rash, you should consult your doctor.
- You should not take acetyl-salicylic acid (aspirin) or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or NSAIDs) if they make your asthma worse.

Use in children

For children 2 to 5 years old, montelukast 4 mg chewable tablets are available.

For children 6 to 14 years old, montelukast 5 mg chewable tablets are available.

Taking other medicines

Some medicines may affect how Glemont works, or Glemont may affect how other medicines work.

Please tell your doctor or pharmacist if you are taking or have recently taken other medicines,

including those obtained without a prescription.

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

- 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 levels in plasma)

Taking Glemont with food and drink

Glemont 10 mg may be taken with or without food.

Pregnancy and breast-feeding

Use in pregnancy

Women who are pregnant or intend to become pregnant should consult their doctor before taking Glemont . Your doctor will assess whether you can take Glemont during this time.

Use in breast-feeding

It is not known if Glemont appears in breast milk. You should consult your doctor before taking Glemont if you are breast-feeding or intend to breast-feed.

Driving and using machines

Glemont is not expected to affect your ability to drive a car or operate machinery. However, individual responses to medication may vary. Certain side effects (such as dizziness and drowsiness) that have been reported very rarely with Glemont may affect some patients' ability to drive or operate machinery.

Important information about some of the ingredients of Glemont

Glemont 10 mg film-coated tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How you take Glemont

- You should take only one tablet of Glemont once a day as prescribed by your doctor.
- It should be taken even when you have no symptoms or have an acute asthma attack.
- Always take Glemont as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- To be taken by mouth.

For adults and adolescents 15 years of age and older:

One 10 mg tablet to be taken daily in the evening. Glemont 10 mg may be taken with or without food.

If you are taking Glemont, be sure that you do not take any other products that contain the same active ingredient, montelukast.

If you take more Glemont than you should

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 and children included abdominal pain, sleepiness, thirst, headache, vomiting, and hyperactivity.

If you forget to take Glemont

Try to take Glemont as prescribed. However, if you miss a dose, just resume the usual schedule of one tablet once daily.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Glemont

Glemont can treat your asthma only if you continue to take it.

It is important to continue taking Glemont for as long as your doctor prescribes. It will help control your asthma.

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

4. Possible side effects

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

In clinical studies with montelukast 10 mg film-coated tablets, the most commonly reported side effects (occurring in at least 1 of 100 patients and less than 1 of 10 patients treated) thought to be related to montelukast were:

- abdominal pain
- headache

These were usually mild and occurred at a greater frequency in patients treated with montelukast than placebo (a pill containing no medication).

The frequency of possible side effects listed below is defined using the following convention:

Very common (affects at least 1 user in 10)

Common (affects 1 to 10 users in 100)

Uncommon (affects 1 to 10 users in 1,000)

Rare (affects 1 to 10 users in 10,000)

Very rare (affects less than 1 user in 10,000)

Additionally, while the medicine has been on the market, the following have been reported:

- upper respiratory infection (Very common)
- increased bleeding tendency (Rare)
- allergic reactions including swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing (Uncommon)
- behaviour and mood related changes [dream abnormalities, including nightmares,

trouble sleeping, sleep walking, irritability, feeling anxious, restlessness, agitation including aggressive behaviour or hostility, depression (Uncommon); tremor, disturbance in attention, memory impairment (Rare); hallucinations, disorientation, suicidal thoughts and actions (Very rare)]

- dizziness, drowsiness, pins and needles/numbness, seizure (Uncommon), palpitations (Rare)
- nosebleed (Uncommon), swelling (inflammation) of the lungs (Very rare)
- diarrhoea, nausea, vomiting (Common); dry mouth, indigestion (Uncommon)
- hepatitis (inflammation of the liver) (Very rare)
- rash (Common); bruising, itching, hives (Uncommon); tender red lumps under the skin most commonly on your shins (erythema nodosum), severe skin reactions (erythema multiforme) that may occur without warning (Very rare)
- joint or muscle pain, muscle cramps (Uncommon)
- fever (Common); weakness/tiredness, feeling unwell, swelling (Uncommon)

In asthmatic patients treated with montelukast, very rare cases of a combination of symptoms such as flu-like illness, pins and needles or numbness of arms and legs, worsening of pulmonary symptoms and/or rash (Churg-Strauss syndrome) have been reported. You must tell your doctor right away if you get one or more of these symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Glemont

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
- HDPE container:
 - Use within 30 days of opening. Once the pack has been opened write the date of opening on the space provided on the package label and also write the date by when the product should be used.
 - Store the medicine in the original package to protect from moisture. This medicinal product does not require any special temperature storage conditions.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Further information

What Glemont contains

- The active substance is montelukast. Each tablet contains montelukast sodium which

corresponds to 10 mg of montelukast.

- The other ingredients are: Microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, Opadry yellow (20A82675)

What Glemont looks like and contents of the pack

Glemont- IR 10 are Round, Beige coloured, biconvex, film coated tablets, engraved with 'G' on one side and '392' on other side.

Nature and contents of the pack:

30 tablets packed in 60 cc HDPE container with 33 mm CRC cap and 1 x 2 g silica gel desiccant along with the leaflet.

Marketing authorisation holder:

Glenmark Pharmaceuticals Limited, B/2, Mahalaxmi Chambers,
22, Bhulabhai Desai road, Mumbai – 400 026

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