

Montiget Chewable Tablets 4mg & 5mg & Montiget Tablets 10mg

Montelukast (4mg, 5mg & 10mg)

What is in this leaflet

1. What Montiget Tablet is used for
2. How Montiget Tablet works
3. Before you use Montiget Tablet
4. How to use Montiget Tablet
5. While you are using it
6. Side effects
7. Storage and Disposal of Montiget Tablet
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Montiget Tablet is used for

Montiget belongs to a group of medicines

that blocks substances in the body called leukotrienes. By blocking leukotrienes, it may help to improve symptoms of asthma and allergic rhinitis.

Montiget does not contain a steroid. It can be used in children 2 years of age and older, teenagers and adults.

Montiget is used to:

- Treat and also to prevent asthma in adults and in children of 2 years of age and older.
- To relief daytime and nighttime symptoms of seasonal allergic rhinitis (nose inflammation).

How Montiget Tablet works

Montiget works by blocking substances in your lungs called leukotrienes which are chemicals your body releases when you breathe in an allergen (such as pollen). These chemicals can cause narrowing and swelling of airways. Blocking leukotrienes improves asthma symptoms, helps prevent asthma attacks and improves seasonal allergic rhinitis symptoms.

Before you use Montiget Tablet

- When you must not use it
When you must not take it

Do not take Montiget if you are allergic or sensitive to:

- Montelukast
- Any of its ingredients

Signs of Allergic reactions include:

- Hives
- Difficulty breathing
- Swelling of your face, lips, tongue, or throat.

Do not give Montiget to children under 2 years of age. Safety and effectiveness in children younger than 2 years of age have not been studied.

Do not take Montiget in the following medical conditions:

- Acute Asthma attack.
- Exercise-Induced Bronchoconstriction (narrowing of airways due to exercising), if it is taken to prevent asthma or allergy symptoms.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

- Before you start to use it

Tell your doctor if:

- You are pregnant or intend to become pregnant. Your doctor will assess whether you can take Montiget during this time. (This information is relevant to the active ingredient, Montelukast).
- You are breast-feeding or plan to breast-feed. It is not known if Montiget passes into breast milk.
- You have or have had any medical conditions.

- You have allergies to any other medicines, foods, preservatives or dyes.
- You have Phenylketonuria. Montiget chewable tablets 4mg and 5mg contain aspartame, a source of phenylalanine.

- Taking other medicines

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may affect how Montiget works, or Montiget may affect your other medicines work.

If you are allergic to aspirin and other Nonsteroidal Anti-Inflammatory Drugs (NSAIDs), you should avoid continue taking NSAIDs because Montiget does not remedy this problem.

How to use Montiget Tablet

- Take Montiget exactly as prescribed by your doctor. Your doctor will tell you how much Montiget to take, and when to take it.
- Do not stop taking Montiget or change when you take it without talking with your doctor.

You can take Montiget with food or without food. Swallow the 10 mg tablet with a glass of water. Chew the 5 mg or 4 mg chewable tablets thoroughly and swallow.

- How much to use

For patients with asthma and/or seasonal allergic rhinitis, take Montiget only when prescribed by your doctor.

- For adults and teenagers 15 years and older, the dose is one 10 mg tablet taken each day.
- For children 6 to 14 years old, the dose is one 5 mg chewable tablet taken each day.
- For children 2 to 5 years old, the dose is one 4 mg chewable tablet taken each day.

- For patients with asthma, take Montiget once a day in the evening.
- For patients with seasonal allergic rhinitis, take Montiget once a day as prescribed by your doctor.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

- When to use it

Asthma:

Take your Montiget at bedtime each day. Taking your tablet at bedtime each day is expected to have the best effect. It will also help you remember when to take the tablets.

Seasonal allergic rhinitis:

Take your Montiget once a day as prescribed by your doctor. Your doctor will advise you on the best time of the day to take your tablet.

Asthma and seasonal allergic rhinitis:

Take your Montiget at bedtime each day if you have both asthma and seasonal allergic rhinitis.

- How long to use it

Montiget must be taken every day because it helps control asthma. Continue giving this medicine to your child for as long as your doctor tells you.

- If you forget to use it

Skip the dose you missed and take your next dose as usual. Do not give a double dose to make up for a forgotten dose.

- If you use too much (overdose)

Immediately contact doctor for advice. No

side effects were reported in the majority of overdose reports. The most frequently occurring symptoms reported with overdose in children included:

- Abdominal pain
- Sleepiness

- Thirst
- Headache
- Vomiting
- Hyperactivity

While you are using it

- Things you must do

- Continue taking Montiget everyday as directed by your doctor, even if you have no asthma symptoms or if you have an asthma attack.
- If your asthma gets worse while taking Montiget, tell your doctor immediately.
- If a sudden (acute) attack of asthma occurs, follow your doctor's instructions on what reliever medicine to use to relieve the attack.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Montiget.

- Things you must not do

- If you have been prescribed the 10 mg tablets, do not take two 5 mg chewable tablets in its place. If you have been prescribed the 5 mg tablets, do not take half a 10 mg tablet in its place. The different strength tablets may not have the same effect, as they are absorbed slightly differently in the body.
- Do not stop taking your medicine or change the dosage without checking with your doctor.
- Do not give Montiget to anyone else, even if they have the same condition as you.

- Things to be careful of

Avoid driving and other hazardous activities, because Montiget causes dizziness.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Montiget. All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Tell your doctor if you notice any of the following

- fluid retention
- nose bleed
- headache, dizziness, drowsiness

Muscle or nerve problems:

- muscle aches or cramps, joint pain

Stomach or bowel problems:

- stomach pain
- nausea, vomiting
- diarrhea

Tell your healthcare provider right away if you notice any of the following behaviour and mood-related changes:

- Obsessive-compulsive symptoms
- tremor
- irritability, restlessness, feeling anxious
- seeing, feeling or hearing things that are not there (also called hallucinations)
- dream abnormalities, difficulty sleeping

These are usually mild side effects of Montiget.

Tell your doctor immediately if you notice any of the following:

- skin rash or itchiness
- increased tendency to bleed, bruising
- fast or irregular heartbeats, also called palpitations

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

If any of the following happen, stop taking Montiget and tell your doctor immediately or go to accident and emergency at your nearest hospital:

- swelling of the face, lips, mouth, throat or tongue which may cause difficulty in breathing or swallowing
- pinkish, itchy swellings on the skin, also called hives

These may be serious side effects. If you have them, you may be having a serious allergic reaction to Montiget. You may need urgent medical attention. These side effects are rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

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 Montiget Tablet

- Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 30°C.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

- Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

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

- What it looks like

Montiget Tablets comes in three types:

Montiget Chewable Tablets 4mg – Light pink to pink colored, round shaped, biconvex tablet engraved “GETZ” on one side and plain on the other side.

Montiget Chewable Tablets 5mg – White colored, round shaped, biconvex tablet engraved “GETZ” on one side and plain on other side.

Montiget Tablets 10mg - Cream to light yellow colored square shaped film coated

tablet having bisect line on one side and plain on other side.

- Ingredients

- Active ingredient

Montelukast Sodium - 4mg

Montelukast Sodium - 5mg

Montelukast Sodium - 10mg

- Inactive ingredients

Montiget Chewable Tablets 4mg

- hypromellose, microcrystalline cellulose, mannitol, ferric oxide red, aspartame, croscarmellose sodium, magnesium stearate, cherry flavor 108B, purified water.

Montiget Chewable Tablets 5mg

- hypromellose, microcrystalline cellulose, mannitol, purified water, aspartame, croscarmellose sodium, cherry flavor 108B, magnesium stearate, purified water.

Montiget Tablets 10mg

- hypromellose, microcrystalline cellulose, lactose regular, croscarmellose sodium, magnesium stearate, opadry II yellow, purified talc, purified water.

- MAL numbers:

Montiget Chewable Tablets 4mg:

MAL14055150AZ

Montiget Chewable Tablets 5mg:

MAL14055148AZ

Montiget Tablets 10mg:

MAL13095077AZ

Manufacturer

Getz Pharma (Pvt) Limited,
29-30/27, Korangi Industrial Area,
Karachi, Pakistan.

Product Registration Holder

Medispec (M) Sdn Bhd
B-1-07, Jalan SS 25/22,
Taman Mayang,
47301 Petaling Jaya, Selangor, Malaysia

Date of revision

15/12/2023

Serial Number

NPRA(R2/1)200109/327