

Package leaflet: Information for the user

Montelair 10 mg film-coated tablets For adolescents and adults from 15 years

Montelukast

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Montelair 10 mg is and what it is used for
2. What you need to know before you take Montelair 10 mg
3. How to take Montelair 10 mg
4. Possible side effects
5. How to store Montelair 10 mg
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1. What Montelair 10 mg is and what it is used for

What Montelair is

Montelair is a leukotriene receptor antagonist that blocks substances called leukotrienes.

How Montelair works

Leukotrienes cause narrowing and swelling of airways in the lungs and also cause allergy symptoms. By blocking leukotrienes, Montelair improves asthma symptoms, helps control asthma and improves seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis).

When Montelair should be used

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

- Montelair is used for the treatment of adults and adolescents 15 years of age and older who are not adequately controlled on their medication and need additional therapy.
- Montelair also helps prevent the narrowing of airways triggered by exercise.
- In those asthmatic patients in whom Montelair is indicated in asthma, Montelair can also provide symptomatic relief of seasonal allergic rhinitis.

Your doctor will determine how Montelair 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 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. What you need to know before you take Montelair 10 mg

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

DO NOT take Montelair

- If you are allergic to montelukast or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Montelair

- If your asthma or breathing gets worse, tell your doctor immediately.
- Oral Montelair 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. Montelair 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.

Various neuropsychiatric events (for example behaviour and mood-related changes, depression and suicidality) have been reported in patients of all ages treated with montelukast (see section 4). If you or your child develop such symptoms while taking montelukast, you should contact your or your child's doctor.

Children and adolescents

Do not give this medicine to children less than 15 years of age.

There are different form(s) of this medicine available for paediatric patients under 18 years of age based on age range.

Other medicines and Montelair

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

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

- 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)

Montelair with food and drink

Montelair 10 mg film-coated tablets may be taken with or without food.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Your doctor will assess whether you can take this medicine during this time.

Breast-feeding

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

Driving and using machines

Montelair 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 with montelukast may affect some patients' ability to drive or operate machinery.

Montelair contains lactose

Montelair 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.

Montelair contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Montelair 10 mg

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 Montelair once a day as prescribed by your doctor.
- It should be taken even when you have no symptoms or have an acute asthma attack.

For adults and adolescents 15 years of age and older:

The recommended dose is one 10 mg tablet to be taken daily in the evening.

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

This medicine is for oral use.

You can take Montelair 10 mg with or without food.

If you take more Montelair 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 Montelair

Try to take Montelair 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 Montelair

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

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

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

4. Possible side effects

Like all medicines, this medicine 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 (may affect up to 1 in 10 people) thought to be related to Montelair 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).

Serious side effects

Talk with your doctor immediately if you notice any of the following side effects with your child, which may be serious, and for which your child may need urgent medical treatment.

Uncommon: the following may affect up to 1 in 100 people

- 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

Rare: the following may affect up to 1 in 1,000 people

- increased bleeding tendency
- tremor
- palpitations

Very rare: the following may affect up to 1 in 10,000 people

- 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) (see section 2)
- low blood platelet count
- behaviour and mood related changes: hallucinations, disorientation, suicidal thoughts and actions
- swelling (inflammation) of the lungs
- severe skin reactions (erythema multiforme) that may occur without warning
- inflammation of the liver (hepatitis)

Other side effects while the medicine has been on the market

Very common: the following may affect more than 1 in 10 people

- upper respiratory infection

Common: the following may affect up to 1 in 10 people

- diarrhoea, nausea, vomiting
- rash
- fever
- elevated liver enzymes

Uncommon: the following may affect up to 1 in 100 people

- behaviour and mood related changes: dream abnormalities, including nightmares, trouble sleeping, sleepwalking, irritability, feeling anxious, restlessness
- dizziness, drowsiness, pins and needles/numbness
- nosebleed
- dry mouth, indigestion
- bruising, itching, hives
- joint or muscle pain, muscle cramps

- bedwetting in children
- weakness/tiredness, feeling unwell, swelling

Rare: the following may affect up to 1 in 1,000 people

- behaviour and mood related changes: disturbance in attention, memory impairment, uncontrolled muscle movements

Very rare: the following may affect up to 1 in 10,000 people

- tender red lumps under the skin most commonly on your shins (erythema nodosum)
- behaviour and mood related changes: obsessive-compulsive symptoms, stuttering

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Montelair

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 blister and outer package. The expiry date refers to the last day of that month.

This medicinal product does not require any special 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. Contents of the pack and other information

What Montelair contains

The active substance is: montelukast (as montelukast sodium).

One film-coated tablet contains montelukast sodium, which is equivalent to 10 mg of montelukast.

The other ingredients are:

Montelair 10 mg film-coated tablets

Tablet core:

Microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, disodium edetate, magnesium stearate

Tablet coating:

Hypromellose, hydroxypropylcellulose, titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172)

What Montelair looks like and contents of the pack

Montelair 10 mg film-coated tablets are beige-coloured, round, biconvex film-coated tablets.

Montelair is available in packs of

Nylon/Alu/PVC - Aluminium blisters:

blister (without weekdays indicated): 10, 20, 30, 50, 60, 90, 100 and 250 tablets

blister (with weekdays indicated): 7, 14, 28, 56, 98, 126 and 154 tablets

HDPE bottles:

10, 20, 30, 50, 60, 90, 100 and 250 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

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Saneca Pharmaceutical a.s., Nitrianska 100, 920 27 Hlohovec, Slovak Republic

This medicinal product is authorised in the Member States of the EEA under the following names:

- AT: Montelukast STADA 10 mg Filmtabletten
- BE: Montelukast Eurogenerics 10 mg filmomhulde tabletten
- CZ: Montelukast Stada 10 mg potahované tablety
- DE: Montelukast STADA 10 mg Filmtabletten
- DK: Montelukast Stada
- ES: MONTELUKAST STADA 10 mg comprimidos recubiertos con película EFG
- FR: MONTELUKAST EG 10 mg comprimé pelliculé
- IE: Montelair 10 mg film-coated tablets
- LU: Montelukast Eurogenerics 10 mg comprimé pelliculé
- PT: Montelucaste Ciclum
- SE: Montelukast STADA, 10 mg filmdagerad

This leaflet was last revised in March 2024.