

**Package leaflet: Information for the user**

**MONTELAIR 5mg Chewable Tablets**

**For children from 6 to 14 years**

Montelukast

Read all of this leaflet carefully before you or your child start(s) 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 your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If you or your child get(s) 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 5 mg is and what it is used for
2. What you need to know before you take MONTELAIR 5 mg
3. How to take MONTELAIR 5 mg
4. Possible side effects
5. How to store MONTELAIR 5 mg
6. Contents of the pack and other information

**1. What MONTELAIR 5 mg is and what it is used for**

MONTELAIR is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, MONTELAIR improves asthma symptoms and helps control asthma.

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

- MONTELAIR is used for the treatment of patients who are not adequately controlled on their medication and need additional therapy.
- MONTELAIR may also be used as an alternative treatment to inhaled corticosteroids for 6 to 14 year old patients who have not recently taken oral corticosteroids for their asthma and have shown that they are unable to use inhaled corticosteroids.
- MONTELAIR also helps prevent the narrowing of airways triggered by exercise.

Your doctor will determine how MONTELAIR should be used depending on the symptoms and severity of you or your child's 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.

## 2. What you need to know before you take MONTELAIR 5 mg

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

### **DO NOT take MONTELAIR**

- If you are or your child is 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 you or your child take MONTELAIR

- If you or your child's 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 or your child. 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 used instead of other asthma medications your doctor has prescribed for you or your child.
- Any patient on anti-asthma medicines should be aware that if you develop a combination of symptoms such as 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 or your child 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.

Patients should be aware that various neuropsychiatric events (for example behaviour and mood-related changes) have been reported in adults, adolescents and children with montelukast (see section 4). If you or your child develop(s) such symptoms while taking MONTELAIR, you should consult your or your child's doctor.

### **Children and adolescents**

For children 2 to 5 years old, MONTELAIR 4 mg chewable tablets.

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

### **Other medicines and MONTELAIR**

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

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

Tell your doctor if you or your child 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 5 mg chewable tablets should not be taken immediately with food; it should be taken at least 1 hour before or 2 hours after food.

### **Pregnancy and breastfeeding**

#### *Use in pregnancy*

Women who are pregnant, think they may be pregnant or are planning to have a baby should ask their doctor for advice before taking this medicine. Their doctor will assess whether they can take this medicine during this time.

### *Use in breast-feeding*

It is not known if MONTELAIR appears in breast milk. Women should consult their doctor before taking MONTELAIR if they are breastfeeding or intend to breastfeed.

### **Driving and using machines**

No studies on the effects on the ability to drive and use machines have been performed.

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

### **MONTELAIR contains aspartame (E951)**

This medicine contains 6 mg aspartame in each chewable tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

### **MONTELAIR contains sodium**

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

## **3. How to take MONTELAIR 5 mg**

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

For children 6 to 14 years of age:

One 5 mg chewable tablet daily to be taken in the evening. MONTELAIR 5 mg chewable tablets should not be taken immediately with food; it should be taken at least 1 hour before or 2 hours after food.

If you or your child is taking MONTELAIR, be sure that you or your child does not take any other products that contain the same active ingredient, montelukast.

MONTELAIR 5 mg chewable tablet may not be used in children below 6 years of age due to insufficient data on safety and efficacy.

### Other available strength/pharmaceutical forms:

4 mg chewable tablets are available for children 2 to 5 years of age.

10 mg film-coated tablets are available for adults 15 years of age and older.

### **If you or your child take(s) 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 or give MONTELAIR to your child**

Try to take MONTELAIR as prescribed. However, if you or your child misses 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 or your child stop(s) taking MONTELAIR**

MONTELAIR can treat you or your child's asthma only if you or your child continues to take it. It is important to continue taking MONTELAIR for as long as your doctor prescribes. It will help control you or your child's 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 5 mg chewable tablets, the most commonly reported side effects (may affect up to 1 in 10 people) thought to be related to MONTELAIR were:

- headache

Additionally, the following side effect was reported in clinical studies with montelukast 10 mg film-coated tablets:

- abdominal pain

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

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

Very common (may affect more than 1 in 10 people)

- upper respiratory infection

Common (may affect up to 1 in 10 people)

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

Uncommon (may affect up to 1 in 100 people)

- allergic reactions including rash, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing
- behaviour and mood related changes [dream abnormalities, including nightmares, irritability, feeling anxious, restlessness, agitation including aggressive behaviour or hostility, depression, trouble sleeping, sleepwalking]
- dizziness, drowsiness, pins and needles/numbness, seizure
- nosebleed
- dry mouth, indigestion
- bruising, itching, hives
- joint or muscle pain, muscle cramps
- weakness/tiredness, feeling unwell, swelling

Rare (may affect up to 1 in 1,000 people)

- increased bleeding tendency
- tremor
- palpitations

Very rare (may affect up to 1 in 10,000 people)

- liver problems (hepatic eosinophilic infiltration)

- hallucinations, disorientation, suicidal thoughts and actions
- hepatitis (inflammation of the liver)
- tender red lumps under the skin most commonly on your shins (erythema nodosum), severe skin reactions (erythema multiforme) that may occur without warning
- stuttering

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.

Ask your doctor or pharmacist for more information about side effects.

#### 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. You can also report side effects directly via HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store MONTELAIR 5 mg**

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.

Store in the original package, in order to protect from light.

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 chewable tablet contains montelukast sodium, which is equivalent to 5 mg montelukast.

The other ingredients are:

Microcrystalline cellulose, mannitol, crospovidone type B, red iron oxide (E172), hydroxypropylcellulose, disodium edetate, cherry flavour, aspartame (E951), talc, magnesium stearate.

#### **What MONTELAIR looks like and contents of the pack**

MONTELAIR 5 mg chewable tablets are pink, round, biconvex tablets with "M5" engraved on one side.

MONTELAIR is available in packs sizes 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**

Takeda Pharma Sp. z.o.o., ul. Ksiestwa Lowickiego 12, 99-420 Lyszkowice, Poland  
STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany  
Centrafarm Services B.V., Nieuwe Donk 9, 4879 AC Etten-Leur, The Netherlands  
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland  
HBM Pharma s.r.o., Sklabinská 30, 036 80 Martin, Slovakia  
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:**

NL: Montelukast CF 5 mg kauwtabletten  
AT: Montelukast STADA 5 mg Kautabletten  
BE: Montelukast Eurogenerics 5 mg kauwtabletten  
CZ: Montelukast Stada 5 mg žvýkačí tablety  
DE: Montelukast STADA junior 5 mg Kautabletten  
DK: Montelukast Stada  
ES: MONTELUKAST STADA 5 mg comprimidos masticables EFG  
FR: MONTELUKAST EG 5 mg comprimé à croquer  
HU: Montelukast Stada 5 mg rágótabletta  
IE: Montelair 5 mg chewable tablets  
LU: Montelukast Eurogenerics 5 mg comprimé à croquer  
PT: Montelucaste Ciclum  
SE: Montelukast STADA, 5 mg tuggtablett

**This leaflet was last revised in May 2019.**