

## Package leaflet: Information for the user

### Montelair 4 mg chewable tablets For children from 2 to 5 years

Montelukast

**Read all of this leaflet carefully before you give this medicine to your child because it contains important information.**

- 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 your child gets 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 4 mg is and what it is used for
2. What you need to know before your child takes Montelair 4 mg
3. How to take Montelair 4 mg
4. Possible side effects
5. How to store Montelair 4 mg
6. Contents of the pack and other information

#### 1. What Montelair 4 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. By blocking leukotrienes, Montelair improves asthma symptoms and helps control asthma.

##### When Montelair should be used

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

- Montelair is used for the treatment of 2 to 5 year old 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 2 to 5 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 for patients 2 years of age and older.

Your doctor will determine how Montelair should be used depending on the symptoms and severity of 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 your child takes Montelair 4 mg

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

### **DO NOT give Montelair to your child**

- If he/she 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 give Montelair to your child.

- If 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 for your child. Always have your child's inhaled rescue medicine for asthma attacks with you.
- It is important that your child takes all asthma medications prescribed by your doctor. Montelair should not be used instead of other asthma medications your doctor has prescribed for your child.
- If your child is on anti-asthma medicines, be aware that if he/she develops 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.
- 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 his/her 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 your child develops such symptoms while taking Montelair, you should consult your child's doctor.

### **Children and adolescents**

Do not give this medicine to children less than 2 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 your child is taking, has recently been given or might be given any other medicines.

Some medicines may affect how Montelair works, or Montelair may affect how your child's other medicines work.

Tell your doctor if your child is 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)

### **Montelair with food and drink**

Montelair 4 mg chewable tablets should not be taken immediately with food; they should be taken at least 1 hour before or 2 hours after food.

### **Pregnancy and breast-feeding**

This subsection is not applicable for the Montelair 4 mg chewable tablets since they are intended for use in children 2 to 5 years of age.

### **Driving and using machines**

This subsection is not applicable for the Montelair 4 mg chewable tablets since they are intended for use in children 2 to 5 years of age, however the following information is relevant to the active ingredient, montelukast.

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 aspartame (E951)**

This medicine contains 4.8 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 4 mg**

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

- This medicine is to be given to a child under adult supervision.
- For children who have problems consuming a chewable tablet, an oral granule formulation is available.
- Your child should take only one chewable tablet of Montelair once a day as prescribed by your doctor.
- It should be taken even when your child has no symptoms or if he/she has an acute asthma attack.

#### **For children 2 to 5 years of age:**

The recommended dose is one 4 mg chewable tablet daily to be taken in the evening. If your child is taking Montelair, be sure that he/she does not take any other medicines that contain the same active ingredient, montelukast.

This medicine is for oral use.

The tablets are to be chewed before swallowing. Montelair 4 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 your child takes more Montelair than he/she should**

Contact your child's 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 give Montelair to your child**

Try to give Montelair as prescribed. However, if your child misses a dose, just resume the usual schedule of one chewable tablet once daily.

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

#### **If your child stops taking Montelair**

Montelair can treat your child's asthma only if he/she continues taking it.

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

If you have any further questions on the use of this medicine, ask your child's 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 4 mg chewable tablets, the most commonly reported side effects (may affect up to 1 in 10 people) thought to be related to Montelair were:

- abdominal pain
- thirst

Additionally, the following side effect was reported in clinical studies with montelukast 10 mg film-coated tablets and 5 mg chewable tablets:

- 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 your child gets 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](http://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.

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 4 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 4 mg chewable tablets are pink, oval, biconvex tablets with "M4" engraved on one side.

Montelair is available in **pack** 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**

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

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:**

- AT: Montelukast STADA 4 mg Kautabletten
- BE: Montelukast Eurogenerics 4 mg kauwtabletten
- CZ: Montelukast Stada 4 mg žvýkácí tablety
- DK: Montelukast Stada
- ES: MONTELUKAST STADA 4 mg comprimidos masticables EFG
- IE: Montelair 4 mg chewable tablets
- LU: Montelukast Eurogenerics 4 mg comprimé à croquer
- PT: Montelucaste Ciclum
- SE: Montelukast STADA, 4 mg tuggtablett

**This leaflet was last revised in August 2022.**