

Package leaflet: information for the patient

**Montelukast OPKO 10 mg tabletten**  
**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 Montelukast OPKO is and what it is used for
2. What you need to know before taking Montelukast OPKO
3. How to take Montelukast OPKO
4. Possible side effects
5. How to store Montelukast OPKO
6. Contents of the pack and other information

**1. What Montelukast OPKO is and what it is used for**

**Name of medicinal product:**

Montelukast OPKO

**What Montelukast OPKO is**

Montelukast OPKO is a leukotriene receptor antagonist that blocks substances called leukotrienes.

**How Montelukast OPKO works**

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

**When Montelukast OPKO should be used**

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

- Montelukast OPKO 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.
- Montelukast OPKO also helps prevent the narrowing of airways triggered by exercise.
- In those asthmatic patients in whom Montelukast OPKO is indicated in asthma, Montelukast OPKO can also provide symptomatic relief of seasonal allergic rhinitis.

Your doctor will determine how Montelukast OPKO 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 Montelukast OPKO**

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

### **DO NOT take Montelukast OPKO:**

- 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 Montelukast OPKO.

- If your asthma or breathing gets worse, tell your doctor immediately.
- Oral Montelukast OPKO 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. Montelukast OPKO 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 develop such symptoms while taking montelukast, you should contact your 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 Montelukast OPKO**

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines including those obtained without a prescription.

Some medicines may affect how Montelukast OPKO works, or Montelukast OPKO may affect how other medicines work.

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

- 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)

### **Montelukast OPKO with food and drink**

Montelukast OPKO 10 mg tablet 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 Montelukast OPKO.

#### Pregnancy

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

#### Breast-feeding

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

### **Driving and using machines**

Montelukast OPKO 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 OPKO may affect some patients' ability to drive or operate machinery.

### **Montelukast OPKO 10 mg tablets contain aspartame and sodium**

Montelukast OPKO contains 0,75 mg aspartame in each 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.

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

## **3. How to take Montelukast OPKO**

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 Montelukast OPKO 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 Montelukast OPKO, 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 Montelukast OPKO 10 mg with or without food.

### **If you take more Montelukast OPKO 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 Montelukast OPKO**

Try to take Montelukast OPKO 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 Montelukast OPKO**

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

It is important to continue taking Montelukast OPKO 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 tablets, the most commonly reported side effects (may affect up to 1 in 10 people) 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).

#### **Serious side effects**

**Talk with your doctor immediately** if you notice any of the following side effects, which may be serious, and for which you 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 to [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Montelukast OPKO**

- 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 after EXP. The first two numbers indicate the month; the last four numbers indicate the year. The expiry date refers to the last date of that month.
- Store in the original package in order to protect from light and 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. Contents of the pack and other information**

### **What Montelukast OPKO contains**

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

corresponds to 10 mg of montelukast.

- The other ingredients are: Mannitol (E 421), microcrystalline cellulose (E 460i), croscarmellose sodium (E 468), aspartame (E 951), cherry flavouring, iron oxide red (E 172), iron oxide yellow (E 172), and magnesium stearate (E 470b),

**What Montelukast OPKO looks like and contents of the pack**

Montelukast OPKO 10 mg tablets are uncoated, round, biconvex, light brown tablets with breaklines on both sides measuring 9.4 mm to 9.8 mm. The breaklines are only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Montelukast OPKO 10 mg is supplied in a carton box containing 2 Alu/Alu blister strips with 14 tablets each.

**Houder van de vergunning voor het in de handel brengen en fabrikant**

**Vergunninghouder:**

OPKO Health Spain S.L.U  
Plaza Europa 13-15  
L'Hospitalet de Llobregat  
08908 Barcelona  
Spanje

**Fabrikant:**

Laboratori Fundacio Dau  
Calle Lletra C De La Zona Franca 12-14  
Poligono Industrial de la Zona Franca De Barcelona  
08040 Barcelona  
Spanje

**In het register ingeschreven onder RVG 130712**

**Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:**

Nederland: Montelukast OPKO 10 mg tabletten  
Spanje: Montelukast OPKO 10 mg comprimidos EFG

**Deze bijsluiter is voor het laatst goedgekeurd in juni 2024**