

## **Package leaflet: Information for the patient**

### **Montul Paediatric 4 mg Chewable Tablets**

montelukast

**Read all of this leaflet carefully before your child starts 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, please 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 child's doctor or pharmacist. This includes any possible side effects not listed in this leaflet (see section 4).

#### **What is in this leaflet**

1. What Montul Paediatric is and what it is used for
2. What you need to know before Montul Paediatric is taken
3. How to take Montul Paediatric
4. Possible side effects
5. How to store Montul Paediatric
6. Contents of the pack and other information

#### **1. What Montul Paediatric is what it is used for**

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

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

- Montul Paediatric 4 mg is used for the treatment of 2 to 5 year old patients who are not adequately controlled on their medication and need additional therapy.
- Montul Paediatric 4 mg 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.
- Montul Paediatric 4 mg also helps prevent the narrowing of airways triggered by exercise for patients 2 years of age and older.

Your doctor will determine how Montul Paediatric 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 Montul Paediatric is taken**

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

**Do not give Montul Paediatric to your child if he/she**

- is allergic (hypersensitive) 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 Montul Paediatric:

- If your child's asthma or breathing gets worse, tell your doctor immediately.
- Oral Montul Paediatric 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 inhaler rescue medicine for asthma attacks with you.
- It is important that your child takes all asthma medications prescribed by your doctor. Montul Paediatric 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.

**Other medicines and Montul Paediatric**

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

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines, including those obtained without a prescription.

Tell your doctor if your child is taking the following medicines before starting Montelukast:

- 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)

**Montul Paediatric with food and drink**

Montul Paediatric 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 Montul Paediatric 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.

*Use in pregnancy*

Women who are pregnant or intend to become pregnant should consult their doctor before taking Montul Paediatric. Your doctor will assess whether you can take Montul Paediatric during this time.

*Use in breast-feeding*

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

**Driving and using machines**

This subsection is not applicable for Montul Paediatric 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.

Montelukast 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.

**Montul Paediatric Chewable Tablets contain aspartame**, which contains a source of phenylalanine. This may be harmful for people with phenylketonuria (a rare, hereditary disorder of the metabolism).

**Montul Paediatric 4 mg Chewable Tablets contain phenylalanine** (equivalent to 0.539 mg phenylalanine per 4 mg chewable tablet).

**Montul Paediatric 4 mg Chewable Tablets contain Allura Red (E129)**. This may cause allergic reactions.

### **3. How to take Montul Paediatric**

- This medicine is to be given to a child under adult supervision.
- Your child should take only one tablet of Montul Paediatric 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.
- Always have your child take Montul Paediatric as your doctor has told you. Check with your child's doctor or pharmacist if you are not sure.
- To be taken by mouth

**The recommended dose is:**

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

One 4 mg chewable tablet daily to be taken in the evening. Montul Paediatric should not be taken immediately with food; it should be taken at least 1 hour before or 2 hours after food. The tablets are to be chewed before swallowing.

If your child is taking Montul Paediatric, be sure that he/she does not take any other medicines that contain the same active ingredient, montelukast.

Montul Paediatric is not recommended below 2 years of age.

- For children 2 to 5 years old, 4 mg chewable tablets and 4 mg granules are available (for children who have problems consuming a chewable tablet).
- For children 6 to 14 years old, 5 mg chewable tablets are available.

#### **If your child takes more Montul Paediatric 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 Montul Paediatric to your child**

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

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

#### **If your child stops taking Montul Paediatric**

Montul Paediatric can treat your child's asthma only if he/she continues taking it. It is important for your child to continue taking Montul Paediatric 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.

**Talk to a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:**

**Uncommon** side effects (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

**Very rare** side effects (may affect up to 1 in 10,000 people):

- suicidal thoughts and actions. Warning signs are e.g. talking about suicide, withdrawing from social contact and wanting to be left alone or feeling trapped or hopeless about a situation
- yellowing of the skin and eyes, unusual tiredness or fever, dark coloured urine caused by inflammation of the liver (hepatitis)
- 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 your child gets one or more of these symptoms.
- severe skin reactions (erythema multiforme) that may occur without warning

In clinical studies with Montelukast 4 mg oral granules, the most commonly reported side effects (may affect up to 1 in 10 people) thought to be related to montelukast were:

- diarrhoea
- hyperactivity
- asthma
- scaly and itchy skin
- rash

Additionally, the following side effects were reported in clinical studies with either 10 mg film-coated tablets and 5 mg or 4 mg chewable tablets:

- abdominal pain
- headache
- thirst

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** side effects (may affect more than 1 in 10 people):

- upper respiratory infection

**Common** side effects (may affect up to 1 in 10 people):

- diarrhoea, nausea, vomiting
- abnormal liver function test results
- rash
- fever

**Uncommon** side effects (may affect up to 1 in 100 people):

- behaviour and mood related changes (dream abnormalities, including nightmares, trouble sleeping, sleep walking, irritability, feeling anxious, restlessness, agitation including aggressive behaviour or hostility, depression)
- dizziness, drowsiness, pins and needles/numbness, seizure
- nosebleed
- dry mouth, indigestion
- bruising, itching, hives
- joint or muscle pain, muscle cramps
- tiredness, feeling unwell, swelling

**Rare** side effects (may affect up to 1 in 1,000 people):

- increased bleeding tendency
- tremor
- disturbance in attention, memory impairment
- palpitations

**Very rare** side effects (may affect up to 1 in 10,000 people):

- hallucinations, disorientation
- swelling (inflammation) of the lungs
- tender red lumps under the skin most commonly on your shins (erythema nodosum)

#### 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 Montul Paediatric**

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 carton after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light and moisture.

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**

- The active substance is montelukast.

Each tablet contains 4 mg montelukast (as montelukast sodium).

- The other ingredients are:  
Mannitol (E421), cellulose microcrystalline, hydroxypropyl cellulose (E 463), iron oxide, red (E 172), croscarmellose sodium, flavour (Cherry Flavour AP0551, Cherry Durarome TD0990B [contains Allura Red, E129]), aspartame (E 951) and magnesium stearate.

## **What Montul Paediatric looks like and contents of the pack**

Montul Paediatric 4 mg are pink to slightly speckled pink, oval tablets with '4' encoded on one side.

Montul Paediatric 4 mg are available in packs of:  
7, 10, 14, 15, 20, 28, 30, 49, 50, 56, 84, 90, 98, 100, 140, 200 chewable tablets

Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder and Manufacturers**

##### **Marketing Authorisation Holder**

Rowex Ltd., Bantry, Co. Cork, Ireland.

##### **Manufacturers**

Salutas Pharma GmbH., Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

Salutas Pharma GmbH., Dieselstrasse 5, 70839 Gerlingen, Germany.

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

LEK S.A., ul. Domaniewska 50C, 02-672 Warszawa, Poland.

Lek Pharmaceuticals d.d., Trimlini 2 D, 9220 Lendava, Slovenia.

Lek S.A., 16 Podlipie Str., 95-010 Stryków, Poland.

S.C. Sandoz S.R.L., Str. Livezeni nr. 7A, 540472 Targu-Mures, Romania.

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

UK	Montelukast HEXAL 4 mg Chewable Tablets
DE	Montelukast HEXAL 4 mg Kautabletten
IE	Montlul Paediatric 4 mg Chewable Tablets
LU	Montelukast HEXAL 4 mg Kautabletten

**This leaflet was last revised in 01/2016.**