

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Montelukast 5 mg Chewable Tablets

montelukast

**Read all of this leaflet carefully before you start giving this medicine to your child because it contains important information for you or for your child.**

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

#### **1. What Montelukast 5 mg Chewable Tablets is and it is used for**

Montelukast 5 mg Chewable Tablets is a leukotriene receptor antagonist that blocks the substance called leukotrienes.

Leukotrienes can cause the narrowing and swelling of airways in your lungs. By blocking leukotrienes, this medicine improves the symptoms and helps control your asthma.

Your doctor has prescribed Montelukast 5 mg Chewable Tablets to treat your child's asthma and to help prevent asthma symptoms during the day and night.

- Montelukast 5 mg Chewable Tablets is used in the treatment of children who are not adequately controlled on their medication and need additional therapy.
- Montelukast 5 mg Chewable Tablets also helps to prevent the narrowing of airways triggered by exercise in children aged from 6 to 14 years of age.
- Montelukast 5 mg Chewable Tablets may also be used as an alternative treatment to inhaled corticosteroids for children aged from 6 to 14 years old who have not recently taken oral corticosteroids to relieve asthma and have shown that they are unable to use inhaled corticosteroids.

Your doctor will determine how Montelukast 5 mg Chewable Tablets should be taken depending on the symptoms and severity of your child's asthma.

#### **What is asthma?**

Asthma is a long-term disease.

Asthma includes:

- Difficulty in breathing because of the narrowed airways. The narrowing of airways can worsen and improve 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 tightness in the chest.

## **2. What you need to know before your child is given Montelukast 5 mg Chewable Tablets**

Please tell your doctor about any medical problems or allergies your child is experiencing now or previously had.

### **Do not give Montelukast 5 mg Chewable Tablets to your child if they:**

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 you or your child take Montelukast 5 mg Chewable Tablets**

- If you or your child's asthma or breathing gets worse, tell your doctor immediately.
- Montelukast 5 mg Chewable Tablets 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 yours or your child's inhaled rescue medicine for asthma attacks with you.
- It is important that you or your child take all asthma medicines prescribed by your doctor. Montelukast 5 mg Chewable Tablets should not be used in place of other asthma medications your doctor has prescribed for you or your child.
- Any patients 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 contact your doctor for advice.
- You or your child should not take acetylsalicylic acid (aspirin) or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or NSAIDs) if they make the asthma symptoms 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 5mg Chewable tablets (see section 4). If your child develop(s) such symptoms while taking Montelukast 5mg Chewable tablets, you should consult your child's doctor.

### **Children and adolescents**

Do not give this medicine to children less than 6 years of age.

For children 6 months to 2 years montelukast 4mg granules are available.

For children 2 to 5 years montelukast 4mg chewable tablets are available.

### **Other medicines and Montelukast 5 mg Chewable Tablets**

Tell your doctor or pharmacist if your child is taking, have recently taken or might take any other medicines, including those medicines obtained without a prescription. This is because some medicines may affect how montelukast works, or montelukast can affect how other medicines work.

Please tell your doctor if your child is taking any of the following medicines before using Montelukast 5 mg Chewable Tablets:

- Phenobarbital (used for treatment of epilepsy)
- Phenytoin (used for treatment of epilepsy)
- Rifampicin (used to treat tuberculosis and some other infections)

### **Montelukast 5 mg Chewable Tablets with food and drink**

This medicine should not be taken immediately with food; it should be taken at least 1-hour before or 2-hours after food.

### **Pregnancy, breast-feeding and fertility**

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

#### *Pregnancy*

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

#### *Breast-feeding*

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

#### **Driving and using machines**

Montelukast is not expected to affect your ability to drive or operate machinery. However, individual responses to the 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.

#### **Montelukast 5 mg Chewable Tablets contains aspartame**

Aspartame is a source of phenylalanine. If your child has phenylketonuria (a rare, hereditary disorder of the metabolism) you should take into account that each tablet contains phenylalanine (equivalent to 0.842 mg/tablet).

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

### **3. How to take Montelukast 5 mg Chewable Tablets**

This medicine is to be given to a child under the supervision of an adult.

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.

- Your child should take only one chewable tablet of this medicine once a day as prescribed by your doctor.
- It should be taken even when your child has no symptoms or has an acute asthma attack.

#### For Children aged 6 to 14 years of age:

One tablet to be taken daily in the evening.

If your child is taking this medicine make sure that your child is not taking other medicines that contain the same active ingredient, montelukast.

This medicine is for oral use.

The tablets are to be chewed before swallowing.

This medicine should not be given immediately with food; it should be given at least 1-hour before or 2-hours after food.

#### **If your child takes more Montelukast 5 mg Chewable Tablets than they 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 (unusually active).

#### **If you forget to give Montelukast 5 mg Chewable Tablets to your child**

Always take this medicine as prescribed by your doctor. However, if you forget to give a dose to your child, just resume the usual schedule of one tablet once daily. Do not give a double dose to make up for a forgotten tablet.

**If you stop giving Montelukast 5 mg Chewable Tablets to your child**

This medicine can treat your child's asthma only if your child continues to take it. It is important to continue taking this medicine for as long as recommended by your doctor. It will help control your child's asthma symptoms.

If you have any further questions on the use of this product, 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 this medicine was:

- headache

Additionally, abdominal pain was reported in clinical studies with Montelukast 10 mg film-coated tablets. 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)

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
- rash
- fever

elevated liver enzymes

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

- nose bleed
- dry mouth
- indigestion
- bruising
- itching
- hives
- joint pain, muscle pain, muscle cramps
- bedwetting in children
- weakness/tiredness
- feeling unwell
- swelling
- feeling dizzy
- feeling drowsy
- pins and needles/ numbness
- 
- Behaviour and mood related changes, such as:
- dream abnormalities (including nightmares)
- trouble sleeping
- sleepwalking
- irritability
- feeling anxious
- restlessness

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

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

**Very rare side effects (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 Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App store. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Montelukast 5 mg Chewable Tablets**

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 abbreviation “EXP” used for expiry date. The expiry date refers to the last day of that month followed by the last four numbers which indicate the year.

Use within 30 days of opening. Once the pack has been opened write the date of opening on the space provided on the package label and also write the date by when the product should be used.

Store in the original package to protect from 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 5 mg Chewable Tablets contains**

- The active substance is montelukast sodium. Each tablet contains montelukast sodium which corresponds to 5 mg of montelukast
- The other ingredients are:  
Mannitol [E421], Cellulose microcrystalline, Hydroxypropylcellulose [E463], Croscarmellose sodium, Cherry flavour, Aspartame [E951], Magnesium stearate.

### **What Montelukast 5 mg Chewable Tablets looks like and contents of the pack**

The 5 mg chewable tablets are white to off white, 9.5 mm diameter round, biconvex uncoated tablets, engraved with ‘G’ on one side and ‘391’ on the other side.

The tablets are packed in HDPE containers which includes a desiccant protecting the tablets from moisture. The desiccant should not be swallowed.

Pack sizes: 20, 28, 30, 50 and 100.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

#### **Marketing Authorisation Holder**

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