

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### MONKASTA

5mg chewable Tablets

MONTELUKAST

For children 6 to 14 years of age

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• 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 •*

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#### What is in this leaflet?

1. What MONKASTA is and what it is used for
2. Before you take MONKASTA
3. How to take MONKASTA
4. Possible side effects
5. How to store MONKASTA

#### 1. WHAT MONKASTA IS AND WHAT IS IT USED FOR

Monkasta tablets are a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, Monkasta tablets improve asthma symptoms and help control asthma.

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

- Monkasta tablets are used for the treatment of 6 to 14 year old patients who are not adequately controlled on their medication and need additional therapy.
- Monkasta tablets 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.
- Monkasta tablets also help prevent the narrowing of airways triggered by exercise for patients 6 to 14 years of age.

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

## 2. BEFORE YOU TAKE MONKASTA

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

### **Do not use Monkasta tablets**

- if you or your child is **allergic** to montelukast or any of the other ingredients of this medicine.
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### **Warnings and precautions**

Talk to your or your child's doctor, pharmacist or nurse before using Monkasta tablets

- If your or your child's asthma or breathing gets worse, tell your or your child's doctor immediately.
- Oral Monkasta tablets are 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 or your child's inhaled rescue medicine for asthma attacks with you/him/her.

- It is important that you or your child take all asthma medications prescribed by your or your child's doctor. Monkasta tablets should not be used instead of other asthma medications your or your child's doctor has prescribed for you/him/her.
- If you or your child is on anti-asthma medicines, be aware that if you or 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 or your child's doctor.
- You or your child should not take acetyl-salicylic acid (aspirin) or other non-steroidal anti-inflammatory drugs (NSAIDs) if they make your or his/her asthma worse.

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### **Other medicines and Monkasta tablets**

Some medicines may affect how Monkasta tablets work, or Monkasta tablets may affect how your or your child's other medicines work.

Please tell your or your child's doctor or pharmacist if you or your child is taking, has recently taken or might take any other medicines.

Tell your doctor if you or your child is taking the following medicines before starting Monkasta tablets:

- 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)
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### **Monkasta tablets with food and drink**

Monkasta tablets should not be taken immediately with food; they should be taken at least one hour before or two hours after food.

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

Pregnancy

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

Breastfeeding

It is not known if Monkasta tablets appears in breast milk. You should consult your doctor before taking Monkasta tablets if you are breast-feeding or intend to breast-feed. Your doctor will assess whether you can take Monkasta tablets during this time.

### **Driving and using machines**

Monkasta tablets are 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 Monkasta tablets may affect some patients' ability to drive or operate machinery.

**Monkasta tablets contain lactose.** If you have been told by your or your child's doctor that you/he/she has an intolerance to some sugars, contact your/his/her doctor before this medicinal product is taken.

### 3. HOW TO TAKE MONKASTA

- Always use this medicine exactly as your or your child's doctor has told you/him/her. Check with your or your child's doctor or pharmacist if you are not sure.
- The recommended dose is one tablet of Montelukast once a day as prescribed by your or your child's doctor.
- It should be taken even when you or your child has no symptoms or if you or your child has an acute asthma attack.
- To be taken by mouth.
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#### **For children 6 to 14 years of age**

One Monkasta tablet daily to be taken in the evening. Monkasta tablets should not be taken immediately with food; it should be taken at least one hour before or two hours after food.

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

#### **For other age groups**

For other age groups, other strengths and pharmaceutical forms of montelukast may be available.

#### **If you or your child takes more Monkasta tablets than you/he/she should**

Contact your or 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 take Monkasta tablets or give Monkasta tablets to your child**

Try to take/give Monkasta tablets as prescribed. However, if you or your child misses a dose, just resume the usual schedule of one tablet once daily.

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

#### **If you or your child stops taking Monkasta tablets**

Monkasta tablets can treat your or your child's asthma only if you or your child continues taking it.

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

If you have any further questions on the use of this product, ask your or your child's doctor or pharmacist.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**If you notice any of the following serious side effects that have been reported with montelukast, stop using Monkasta tablets and contact a doctor immediately:**

- sudden wheezing, swelling of lips, tongue and throat or body, rash, fainting or difficulties to swallow (severe allergic reaction). This side effect is uncommon (may affect up to 1 in 100 people).
- flu-like illness, pins and needles or numbness of arms and legs, worsening of pulmonary symptoms and/or rash (Churg-Strauss syndrome). This side effect is very rare (may affect up to 1 in 10,000 people).
- suicidal thoughts and actions. This side effect is very rare (may affect up to 1 in 10,000 people).
- severe skin reactions (erythema multiforme) that may occur without warning. This side effect is very rare (may affect up to 1 in 10,000 people).

The following side effects have also been reported with montelukast:

**Very common:** may affect more than 1 in 10 people

- Colds (upper respiratory infection)

**Common:** may affect up to 1 in 10 people

- Headache
- Abdominal pain
- Thirst
- Diarrhoea, nausea, vomiting
- Rash
- Fever
- Asthma
- Hyperactivity
- Red, itchy skin (eczema)
- Increased amounts of certain substances in the blood (transaminases)

**Uncommon:** 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, seizures (fits)
- Nosebleed
- Dry mouth, indigestion
- Bruising, itching, hives
- Joint or muscle pain, muscle cramps
- Tiredness, feeling unwell, swelling

**Rare:** may affect up to 1 in 1,000 people

- Tremor, disturbance in attention, memory impairment
- Increased bleeding tendency
- Shaking
- Feeling your heartbeat (palpitations)
- Swelling of the skin

**Very rare:** may affect up to 1 in 10,000 people

- Hallucinations, confusion
- Hepatitis (inflammation of the liver), liver problems (hepatic eosinophilic infiltration)
- Tender red lumps under the skin most commonly on your shins (erythema nodosum)

#### **Reporting of side effects**

If you or your child gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. HOW TO STORE MONKASTA**

- 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 and blister 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 store above 30°C.
- 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.