Package leaflet: Information for the user

Montelukast 10 mg Film-coated Tablets

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

1. What Montelukast is and what it is used for

Montelukast contains the active substance montelukast sodium. Montelukast is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs and also cause allergy symptoms. By blocking leukotrienes, Montelukast improves asthma symptoms, helps control asthma and improves seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis).

Your doctor has prescribed Montelukast to treat asthma, preventing your asthma symptoms during the day and night.
- Montelukast is used for the treatment of patients who are not adequately controlled on their medication and need additional therapy.
- Montelukast also helps prevent the narrowing of airways triggered by exercise.
- In those asthmatic patients in whom Montelukast is indicated in asthma, Montelukast can also provide symptomatic relief of seasonal allergic rhinitis

Your doctor will determine how Montelukast 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 the 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

Do not take Montelukast
- 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
- If your asthma or breathing gets worse, tell your doctor immediately.
- Oral Montelukast 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 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.

Children
Montelukast should not be used in children below 15 years of age.

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

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

Tell your doctor if you are 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).

Montelukast with food
Montelukast 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 this medicine.

Use in pregnancy
Your doctor will assess whether you can take Montelukast during pregnancy.

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

Driving and using machines
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.

Montelukast contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Montelukast

- You should take only one tablet of Montelukast once a day as prescribed by your doctor.
- It should be taken even when you have no symptoms or have an acute asthma attack.
- Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- To be taken by mouth.

For adults 15 years of age and older:
One 10 mg tablet to be taken daily in the evening. Montelukast may be taken with or without food.

If you are taking Montelukast be sure that you do not take any other products that contain the same active ingredient, montelukast.

If you take more Montelukast 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
Try to take Montelukast 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
Montelukast can treat your asthma only if you continue to take it.

It is important to continue taking Montelukast 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.

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Montelukast 10 mg film-coated tablets

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2D Code Area

Montelukast 10 mg film-coated tablets

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4. Possible side effects

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

In clinical studies with montelukast, the most commonly reported side effects (occurring in at least 1 of 100 patients and less than 1 of 10 patients treated) 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 sodium than placebo (a pill containing no medication).

Additionally, while the medicine has been on the market, the following have been reported:

Very common: may affect more than 1 in 10 people
- upper respiratory infection

Common: may affect up to 1 in 10 people
- increased levels of liver enzymes (ALT, AST)
- diarrhoea, nausea, vomiting
- rash
- fever

Uncommon: 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 [dream abnormalities, including nightmares, trouble sleeping, sleep walking, irritability, feeling anxious, restlessness, agitation including aggressive behaviour or hostility, depression, hyperactivity including irritability, restlessness, tremors
- dizziness, drowsiness, pins and needles/numbness, seizure
- nosebleed
- dry mouth, indigestion
- bruising, itching, hives
- joint or muscle pain, muscle cramps
- weakness/tiredness, feeling unwell, swelling

Rare: may affect up to 1 in 1,000 people
- increased bleeding tendency
- disturbance in attention, memory impairment
- palpitations
- giant hives

Very rare: may affect up to 1 in 10,000 people
- hallucinations, disorientation, suicidal thoughts and actions
- hepatitis (inflammation of the liver)
- tender red lumps under the skin most commonly on your shins (erythema nodosum), severe skin reactions (erythema multiforme) that may occur without warning
- liver eosinophilic infiltration(liver injury)

In asthmatic patients treated with montelukast, very rare cases of 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 you get one or more of these symptoms.

Ask your doctor or pharmacist for more information about side effects. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Montelukast

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/carton/label. 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

What Montelukast contains
The active substance is montelukast. Each film-coated tablet contains 10 mg of montelukast (as sodium).

The other ingredients are lactose monohydrate, cellulose, microcrystalline (Avicel PH 102) (E -460), croscarmellose sodium (E-463), Hydroxypropylcellulose (Klucel LF) (E-463), magnesium stearate, Opadry Yellow 04F -82591 as film-coating.

Ingredients of Opadry Yellow: HPMC 2910/Hypromellose 15 cP, titanium dioxide (E171), macrogol/PEG 6000, iron oxide yellow (E172), iron oxide red (E172).

What Montelukast looks like and contents of the pack
Montelukast are beige coloured, square shaped, biconvex, film coated tablets which are plain on both sides.

Length: 8.1 mm ± 0.2 mm
Breadth: 8.1 mm ± 0.2 mm

Packaged in plain laminated 3 Ply Alu - Alu film blister (consisting of nylon/aluminum/PVC and Al. Blister Foil) package in:

Blisters in packages of: 20, 28, 30, 50, 56, 98 and 100 tablets.

Blisters (unit doses), in packages of: 50 and 56 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Cipla (EU) Limited.
Hillbrow House, Hillbrow Road,
Esher, Surrey, KT10 9NW, United Kingdom.

Manufacturer

S & D Pharma CZ,spol.s. r.o.,
Theodar 28,
273 08 Pchery (Pharmos a.s. facility),
Czech Republic

Cipla (EU) Limited
4th Floor, 1 Kingdom Street, London, W2 6BY,
United Kingdom

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

United Kingdom	Montelukast 10 mg Film-coated Tablets
Malta	Montelukast 10 mg Film-coated Tablets
Ireland	Montelukast 10 mg Film-coated Tablets
Cyprus	Montelukast Cipla 10 mg επικαλυμμένα με λεπτό υμένιο δισκία
Czech Republic	Montelukast Cipla 10 mg potahované tablety
Slovakia	Montelukast Cipla 10 mg filmom obalené tablety
Hungary	Montelukast Cipla 10 mg filmtabletta
Bulgaria	Монтелукаст Cipla 10 мг филмирани таблетки
Romania	Montelukast Cipla 10 mg comprimate filmate
Slovenia	Montelukast Cipla 10 mg filmsko obložene tablete
Croatia	Montelukast Cipla 10 mg filmom obložene tablete

This leaflet was last revised in 12/2014.

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PACKAGING DEVELOPMENT

Product Name : Montelukast 10mg	**Item Code : XXXXX**	**Item : PIL**	**Date : 14-01-15**
Coordinator : Shweta	**Artist : Atul**	**Software : Illustrator CS5**	
Fonts : Convert to curve			
Colours : **BLUE WOOL TEST VALUE 5-8 (LIGHT FASTENING DATA)** Pantone Black C			
Spectro-Densitometer Delta-E reading (ΔE) for colour: NOT MORE THAN dE2.5	**Glossmeter reading (for white surface): NOT LESS THAN 80 %**		
Supersedes / Reference : **Screen : # 150** **Unwinding Direction :**			
Tuck flap: **Side / Collar flap overlap:** **Caliper (Thickness) for Board:**			
Links :			
Pharmacode :	**Design : Folded**		
Material : 54 GSM JK Maplitho Paper.	**Varnish :**		
Actual Size : 335 x 250mm	**Size after Folding : 37 x 31mm**		
Print repeat length :			
Grain Direction : Perpendicular to Crease / Perpendicular to Pasting Flap / Parallel to length			
Reference / Instructions / Remark / Braille Text Embossing:			
Artwork Print Size: ☐ actual ☐ scaled			
Path : mac/Cipla (EU)/Own Launch/ Montelukast 10mg Tablets Cipla (EU) IE PIL.ai			

Checked by	Artist	Cordinator	Section Head	File Copied by:	file loaded in BCT HO
Pharma Code	☐	☐			
2D Code	☐	☐			
Barcode Code	☐	☐			
Artwork	☐	☐			
Spell check	☐	☐		Date:	

NOTE TO THE PRINTER :

- **Return approved artwork alongwith the proof.**
- **The proof must be verified against the approved hardcopy, should be certified and signed by an authorised QA person. The unsigned proof will not be accepted.**
- **Colour scheme must be as approved by packaging development co-ordinator.**
- **Any deviation must be brought to the notice of packaging development co-ordinator immediately.**
- **For any clarification, please contact packaging development co-ordinator immediately.**

Font : Times New Roman (Regular) **Times New Roman (Bold)**
Heading : 12pt
Subheading : 10pt
Body text: 9pt