

SINGULAIR® 10mg film-coated tablets

(montelukast)

Patient Information Leaflet

Read all of this leaflet carefully before you start using 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 Singulair is and what it is used for
- 2 What you need to know before you take Singulair
- 3 How to take Singulair
- 4 Possible side effects
- 5 How to store Singulair
- 6 Contents of the pack and other information

1 What Singulair is and what it is used for

What Singulair is

Singulair is a leukotriene receptor antagonist that blocks substances called leukotrienes.

How Singulair works

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

When Singulair should be used

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

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

Your doctor will determine how Singulair 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 Singulair

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

Do not take Singulair

- * if you are allergic (hypersensitive) to montelukast or any of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Singulair.

- * If your asthma or breathing gets worse, tell your doctor immediately.
- * Oral Singulair 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. Singulair 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 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 Singulair

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 Singulair works, or Singulair may affect how other medicines work.

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

- * 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)

Singulair with food and drink

Singulair 10 mg film-coated 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 Singulair.

Pregnancy

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

Breast-feeding

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

Driving and using machines

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

Singulair 10 mg film-coated tablets contain 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 Singulair

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 Singulair 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 Singulair, 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 Singulair 10 mg with or without food.

If you take more Singulair 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 Singulair

Try to take Singulair as prescribed. However, if you miss a dose, just resume the usual schedule of one tablet once daily.

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Patient Information Leaflet (continued)

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

If you stop taking Singulair

Singulair can treat your asthma only if you continue to take it. It is important to continue taking Singulair for as long as your doctor prescribes. It will help control your asthma.

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 Singulair 10 mg film-coated tablets, 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 Singulair were:

- * abdominal pain
- * headache

These were usually mild and occurred at a greater frequency in patients treated with Singulair than placebo (a pill containing no medication).

The frequency of possible side effects listed below is defined using the following convention:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

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

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

Not known: frequency cannot be estimated from the available data

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

- * upper respiratory infection (*Very common*)
- * increased bleeding tendency (*Rare*)
- * allergic reactions including swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing (*Uncommon*)
- * behaviour and mood related changes [dream abnormalities, including nightmares, trouble sleeping, sleepwalking, irritability, feeling anxious, restlessness, agitation including aggressive behaviour or hostility, depression (*Uncommon*); tremor, disturbance in attention, memory impairment (*Rare*); hallucinations, disorientation, suicidal thoughts and actions (*Very rare*)]
- * dizziness, drowsiness, pins and needles/numbness, seizure (*Uncommon*)
- * palpitations (*Rare*)
- * nosebleed (*Uncommon*), swelling (inflammation) of the lungs (*Very rare*)
- * diarrhoea, nausea, vomiting (*Common*); dry mouth, indigestion (*Uncommon*)
- * hepatitis (inflammation of the liver) (*Very rare*)
- * rash (*Common*); bruising, itching, hives (*Uncommon*); tender red lumps under the skin most commonly on your shins (erythema nodosum), severe skin reactions (erythema multiforme) that may occur without warning (*Very rare*)
- * joint or muscle pain, muscle cramps (*Uncommon*)
- * fever (*Common*); weakness/tiredness, feeling unwell, swelling (*Uncommon*)

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 (See section 2).

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 HPRAs 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 Singulair

Keep out of the sight and reach of children.

Do not store above 30°C.

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

Do not use Singulair after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Contents of the pack and other information

What Singulair contains

The active substance is montelukast. Each tablet contains montelukast sodium which corresponds to 10 mg of montelukast.

The other ingredients are:

Microcrystalline cellulose, lactose monohydrate (89.3 mg), croscarmellose sodium, hydroxypropylcellulose (E463), and magnesium stearate.

Film coating: hypromellose, hydroxypropylcellulose (E463), titanium dioxide (E 171), red ferric oxide (E 172), yellow ferric oxide (E 172) and carnauba wax.

What Singulair looks like and the contents of the pack

Singulair tablets are beige, rounded square, film-coated with SINGULAIR engraved on one side and MSD 117 on the other.

Blisters in packages of 28.

The Parallel Product Authorisation Holder is:

LTT Pharma Limited, Unit 18 Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

Re-packaged by:

Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

Manufacturer:

This medicine is manufactured by Merck Sharp & Dohme Ltd, Cramlington, Northumberland NE23 3JU, Great Britain.

SINGULAIR is a registered trademark of Merck Sharp & Dohme Corp.

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Blind or partially sighted?

Is this leaflet hard to see or read?

Phone LTT Pharma Limited,

Tel: +44 (0) 1527 505414 for help.

Information is given by:

The Asthma Society of Ireland, Eden House, 15-17 Eden Quay, Dublin 1. Alternatively phone The Asthma Live Line on 01 8788122, Monday, Wednesday, Thursday 10am to 1pm, or 01 8788511 9am to 5pm, or The Asthma Line on callsave 1850 44 5464.

(The Asthma Society of Ireland is independent charity working to conquer asthma and is not associated with Merck Sharp & Dohme Limited.)

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

Austria, Belgium, Denmark, Estonia, Finland, France, Greece, Hungary, Spain, Sweden, Germany, Ireland, UK, Italy, Luxembourg, Netherlands, Norway, Poland, Portugal

Singulair