

PACKAGE LEAFLET: INFORMATION FOR THE USER

SINGULAIR® 10mg film-coated tablets (montelukast)

Your medicine is available using the above name but will be referred to as Singulair throughout this leaflet.

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

In this leaflet:

- What Singulair is and what it is used for
- Before you take Singulair
- How to take Singulair
- Possible side effects
- How to store Singulair
- Contents of the pack and other information

1. What Singulair is and what it is used for

Singulair 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, Singulair improves asthma symptoms, helps control asthma and improves seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis).

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

- Singulair is used for the treatment of patients 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. 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 the other ingredients of Singulair (see 6. Contents of the pack and other information).

Take special care with 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.

Use in children

For children 2 to 5 years old, Singulair Paediatric 4mg chewable tablets and Singulair Paediatric 4mg granules are available.

For children 6 to 14 years old, Singulair Paediatric 5mg chewable tablets are available.

Taking other medicines

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

Please tell your doctor or pharmacist if you are taking or have recently taken other medicines, including those obtained without a prescription.

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)

Taking Singulair with food and drink

Singulair may be taken with or without food.

Pregnancy and breast-feeding

Use in pregnancy

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

Use in 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.

Important information about some of the ingredients of Singulair

Singulair 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 Singulair

- 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.
- Always take Singulair as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- To be taken by mouth

For adults and adolescents 15 years of age and older:

One 10mg tablet to be taken daily in the evening. Singulair may be taken with or without food.

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

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.

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, Singulair can cause side effects, although not everybody gets them.

In clinical studies with Singulair, 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 (affects at least 1 user in 10)

Common (affects 1 to 10 users in 100)

Uncommon (affects 1 to 10 users in 1,000)

Rare (affects 1 to 10 users in 10,000)

Very rare (affects less than 1 user in 10,000)

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.

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, 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 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 use this medicine after the expiry date ('Exp') which is stated on the blister and carton labels. The first two numbers indicate the month; the last four numbers indicate the year. This medicine expires at the end of the month shown.
- Do not store above 30°C.
- Store in the original package in order to protect from light and moisture.
- If your tablets appear to be discoloured or show any other signs of deterioration, please return to your pharmacist who will advise you further.
- 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

- Each film-coated tablet contains montelukast sodium equivalent to 10mg of montelukast.
- The other ingredients are: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, hypromellose (E463) and magnesium stearate.
Film coating: hypromellose, hypromellose (E463), titanium dioxide (E171), red iron oxide (E172), yellow iron oxide (E172) and carnauba wax.

What Singulair looks like and contents of the pack

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

Singulair is available in blister packs of 28 tablets.

Manufacturer

Manufactured by: Merck Sharp & Dohme Ltd., Cramlington, Northumberland, NE23 3JU, UK.

Procured from within the EU by the PPA holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

Repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR, UK.

Distributed by: Eurodrug Ltd., Santry, Dublin 9.

PPA No: 1151/203/3

Information is given by:

In UK: Asthma UK, Providence House, Providence Place, London N1 ONT. Alternatively phone the Asthma UK Adviceline on 08457 010203, Monday to Friday 9 am to 5 pm, calls charged at local rate.

In Ireland: 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 UK and The Asthma Society of Ireland are independent charities working to conquer asthma and are not associated with Merck Sharp & Dohme Limited or Imbat Ltd.)

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

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

SINGULAIR

Leaflet revision and issue dated (ref): 29.10.14

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