

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What SINGULAIR 10 mg film-coated tablets is and what it is used for
2. Before you take SINGULAIR 10 mg film-coated tablets
3. How to take SINGULAIR 10 mg film-coated tablets
4. Possible side effects
5. Storing SINGULAIR 10 mg film-coated tablets

SINGULAIR® 10 mg Film-coated Tablets
(montelukast)

Each tablet contains as active substance montelukast (in sodium salt form) 10 mg.

The excipients are microcrystalline cellulose, lactose monohydrate (89,3 mg), croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, hypromellose, titanium dioxide (E 171), red ferric oxide and yellow ferric oxide (E 172) and carnauba wax.

License holder:

MERCK SHARP & DOHME DE ESPAÑA, S.A.
C/ Josefa Valcárcel, 38
28027 MADRID

Manufacturing responsible:

MERCK SHARP & DOHME, Ltd.
Shotton Lane
Cramlington
Northumberland, NE23 3JU
UNITED KINGDOM

1. WHAT SINGULAIR 10 mg FILM-COATED TABLETS IS AND WHAT IT IS USED FOR

SINGULAIR 10 mg is available in package of 28 tablets.

SINGULAIR belongs to a group of drugs called leukotriene receptor antagonists.

SINGULAIR 10 mg is used for the treatment of asthma in patients who are not adequately controlled on their medication and need additional therapy. SINGULAIR 10 mg also helps prevent the narrowing of airways triggered by exercise. In those asthmatic patients in whom SINGULAIR 10 mg is indicated in asthma, SINGULAIR 10 mg can also provide symptomatic relief of seasonal allergic rhinitis.

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2. BEFORE YOU TAKE SINGULAIR 10 mg FILM-COATED TABLETS

Do not take SINGULAIR 10 mg:

- If you are allergic to any of its components.

Take special care with SINGULAIR 10 mg:

If during treatment with SINGULAIR 10-mg the asthma symptoms get worse, you should contact your doctor immediately.

If during treatment with anti-asthma medicines you develop a combination of symptoms including a flu-like illness, pins and needles or numbness of arms or legs, and/or rash, you should consult your doctor.

If you have an acute asthma attack:

The appropriate treatment for an acute asthma attack is an inhalation drug (short-acting β -agonist) that your doctor has prescribed for that purpose.

If an acute asthma attacks occurs in a patient **not** taking SINGULAIR 10-mg, oral SINGULAIR should never be used to treat the acute asthma attack.

However, in a patient treated with SINGULAIR 10-mg, it is important that you continue taking SINGULAIR 10-mg daily as prescribed by your doctor, even if you have an asthma attack.

Taking SINGULAIR 10 mg with food and drink:

SINGULAIR 10 mg may be taken with or without food.

Pregnancy:

Women who are pregnant or intend to become pregnant should consult their doctor before taking SINGULAIR 10 mg.

Consult your doctor or pharmacist before taking a medicine.

Breast-feeding:

It is not known if SINGULAIR 10 mg appears in breast milk, therefore, patients should consult their doctor during the breast-feeding period before taking SINGULAIR 10 mg

Consult your doctor or pharmacist before taking a medicine.

Driving and using machines:

SINGULAIR 10 mg is not expected to affect your ability to drive or operate machinery. However, individual responses to medication may vary. Certain side effects that have been reported very rarely with SINGULAIR may affect some patient's ability to drive or operate machinery.

Children:

This formulation is not intended for children. Other presentations are available (SINGULAIR 5 mg Pediatric and SINGULAIR 4 mg chewable tablets) adequate for children 6 to 14 years old and 2 to 5 years of age, respectively. Safety and effectiveness of SINGULAIR have not been established in children less than 2 years old.

Important information about some of the ingredients of SINGULAIR 10 mg:

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.

Taking other medicines:

In general, SINGULAIR 10 mg does not interfere with other medicines that you may be taking. It is important, however, to tell your doctor about all drugs that you are using or plan to use, including those obtained without a prescription. In particular, tell your doctor if you are taking phenobarbital, phenytoin or rifampicin.

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines - even those not prescribed.

3. HOW TO TAKE SINGULAIR 10 mg FILM-COATED TABLETS

Follow these instructions unless your doctor has given you different indications.

Inform your doctor about any medical problem or allergy you have or have had.

Remember to take the medicine.

SINGULAIR 10-mg should be taken as prescribed by the doctor.

Take only one tablet of SINGULAIR once a day as prescribed by your doctor.

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

Dosage for patients 15 years of age and older: One 10 mg tablet daily to be taken in the evening. SINGULAIR 10 mg may be taken with or without food.

Since SINGULAIR 10-mg treatment is a chronic maintenance treatment, it is important that you continue taking SINGULAIR 10-mg daily as prescribed by your doctor, even when you have no symptoms or if you have an episode of asthma attack (in the latter case, the appropriate treatment should be used to treat the asthma attack).

It is important that you take all asthma medications prescribed by your doctor. SINGULAIR 10-mg should not be substituted for other asthma medications your doctor has prescribed you.

If you have the impression that the effect of SINGULAIR 10 mg is too strong or too weak, talk to your doctor or pharmacist.

If you take more SINGULAIR 10 mg than you should:

In case of overdose or accidental intake consult the Information Service of Toxicology, tel.: (91) 562-0420. Also contact your doctor immediately.

If you forget to take SINGULAIR 10 mg:

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 forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

Like all medicines, SINGULAIR 10 mg may have side effects.

SINGULAIR is generally well-tolerated. In studies, the most commonly reported side effects thought to be related to SINGULAIR were abdominal pain, headache, and thirst. Additionally, the following have been reported very rarely: allergic reactions including rash, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing, itching, and hives; tiredness, restlessness, agitation including aggressive behavior, irritability, dizziness, drowsiness, hallucinations, dream abnormalities, including nightmares and trouble sleeping, pins and needles/numbness, seizure; feeling unwell, joint or

muscle pain, muscle cramps, dry mouth, nausea, vomiting, indigestion, diarrhoea, hepatitis; increased bleeding tendency, bruising, palpitations; and swelling.

These were usually mild and occurred as often in patients treated with SINGULAIR or placebo (a pill containing no medication).

If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING SINGULAIR 10 mg FILM-COATED TABLETS

Keep out of the reach and sight of children.

Store in the original package.

Expiration:

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