

**SINGULAIR® 10 mg Tablet**  
(montelukast)

**ABRIDGED PRESCRIBING INFORMATION**

Refer to Summary of Product Characteristics (SPC) before prescribing

**Adverse events should be reported. Reporting forms and information can be found at [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk). Adverse events should also be reported to Merck Sharp & Dohme Limited (01992-467272).**

**PRESENTATIONS**

‘Singulair’ Tablets containing montelukast sodium, equivalent to 10 mg montelukast.

**USES**

Treatment of asthma as add-on therapy in those patients with mild to moderate persistent asthma inadequately controlled on inhaled corticosteroids and in whom ‘as needed’ short-acting  $\beta_2$ -agonists provide inadequate clinical control. In those asthmatic patients where ‘Singulair’ is indicated in asthma, ‘Singulair’ can also provide symptomatic relief of seasonal allergic rhinitis.

Also for the prophylaxis of asthma where the predominant component is exercise-induced bronchoconstriction.

**DOSAGE AND ADMINISTRATION**

*Adults 15 years of age and older with asthma, or with asthma and concomitant seasonal allergic rhinitis:* one ‘Singulair’ 10 mg tablet daily in the evening with or without food.

Patients should continue taking ‘Singulair’ even when asthma is under control as well as during periods of worsening asthma.

‘Singulair’ 10 mg tablets should not be used concomitantly with other products containing the same active ingredient, montelukast.

*Therapy with ‘Singulair’ in relation to other treatments for asthma.*  
‘Singulair’ can be added to a patient’s existing treatment regimen.

*$\beta_2$ -agonist therapy:* ‘Singulair’ can be added to the treatment regimen of patients who are not adequately controlled on ‘as needed’ short-acting  $\beta_2$ -agonist.

*Inhaled corticosteroids:* ‘Singulair’ can be used as add-on therapy when inhaled corticosteroids provide inadequate clinical control. ‘Singulair’ should not be abruptly substituted for inhaled corticosteroids.

## CONTRA-INDICATIONS

Hypersensitivity to montelukast or any of the excipients.

## PRECAUTIONS

‘Singulair’ should never be used to treat acute asthma attacks. Patients should be advised to have appropriate rescue medication available. If an attack occurs, a short-acting inhaled  $\beta_2$ -agonist should be used.

‘Singulair’ should not be substituted abruptly for inhaled or oral corticosteroids.

The possibility that leukotriene receptor antagonists may be associated with the emergence of Churg-Strauss syndrome can neither be excluded nor established. Physicians should be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications and/or neuropathy presenting in their patients.

Patients with aspirin-sensitive asthma must continue to avoid taking aspirin and other non-steroidal anti-inflammatory drugs.

‘Singulair’ 10 mg tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

*Interactions:* Use with caution, especially in children, when given with CYP 3A4 inducers (such as phenytoin, phenobarbital and rifampicin).

*In vitro* studies have shown montelukast is a potent inhibitor of CYP 2C8. However, data from a clinical drug-drug interaction study involving montelukast and rosiglitazone (a probe substrate representative of medicinal products primarily metabolised by CYP 2C8) demonstrated that montelukast does not inhibit CYP 2C8 *in vivo*. Therefore, montelukast is not anticipated to alter the metabolism of medicinal products metabolised by this enzyme (e.g. paclitaxel, rosiglitazone, and repaglinide.)

*Use in pregnancy and lactation:* Animal studies do not indicate harmful effects on pregnancy or embryonal/foetal development. Limited data from pregnancy databases do not suggest causal relationship between ‘Singulair’ and limb defect malformations that have been rarely reported in worldwide post-marketing experience.

Studies in rats have shown that montelukast is excreted in milk. It is not known if montelukast is excreted in human milk.

‘Singulair’ may be used during pregnancy and in breast-feeding only if considered to be clearly essential.

## SIDE EFFECTS

**Refer to SPC for complete information on side effects.**

Side effects, usually mild, generally did not require discontinuation of therapy.

*'Singulair' 10 mg tablets*

'Singulair' 10 mg tablets have been evaluated in approximately 4,000 asthmatic patients and 400 asthmatic patients with seasonal allergic rhinitis, aged 15 years and older. In two similarly designed trials, only abdominal pain and headache were commonly reported as drug-related.

*'Singulair' Paediatric 5 mg chewable tablets*

In clinical studies in paediatric patients 6 to 14 years of age, the only adverse experiences commonly reported as drug-related in patients treated with montelukast was headache.

With prolonged treatment in clinical trials with a limited number of patients for up to 2 years for adults and up to 12 months for paediatric patients 6 to 14 years of age, the safety profile did not change.

The following adverse reactions have been reported in post-marketing use:

*Infections and infestations:* upper respiratory infection

*Blood and lymphatic system disorders:* increased bleeding tendency

*Immune system disorders:* hypersensitivity reactions including anaphylaxis, hepatic eosinophilic infiltration

*Psychiatric disorders:* dream abnormalities including nightmares, hallucinations, insomnia, somnambulism, irritability, anxiety, restlessness, agitation including aggressive behaviour or hostility, tremor, depression, suicidal thinking and behaviour (suicidality) in very rare cases

*Nervous system disorders:* dizziness, drowsiness, paraesthesia/hypoesthesia, seizure

*Cardiac disorders:* palpitations

*Respiratory, thoracic and mediastinal disorders:* epistaxis

*Gastro-intestinal disorders:* diarrhoea, dry mouth, dyspepsia, nausea, vomiting

*Hepato-biliary disorders:* elevated levels of serum transaminases (ALT, AST) hepatitis (including cholestatic, hepatocellular, and mixed-pattern liver injury)

*Skin and subcutaneous tissue disorders:* angioedema, bruising, urticaria, pruritus, rash, erythema nodosum

*Musculoskeletal disorders:* arthralgia, myalgia including muscle cramps

*General disorders and administration site conditions:* asthenia/fatigue, malaise, oedema, pyrexia

Very rare cases of Churg-Strauss Syndrome (CSS) have been reported during treatment in asthmatic patients.

## **PACKAGE QUANTITIES AND BASIC NHS COST**

‘Singulair’ 10 mg tablets: £26.97 for 28 tablets

## **Marketing Authorisation Numbers:**

‘Singulair’ 10 mg Tablets: PL 0025/0358

## **Marketing Authorisation Holder:**

Merck Sharp & Dohme Limited  
Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, UK.

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