

corticosteroids, and smoking cessation if clinically appropriate.

Patients currently receiving omalizumab whose disease does not meet the criteria should be able to continue treatment until they and their clinician consider it appropriate to stop.

www.nice.org.uk/TA278

▶ **Omalizumab for previously treated chronic spontaneous urticaria (June 2015) NICE TA339**

Omalizumab is an option as add-on therapy for the treatment of severe chronic spontaneous urticaria in patients 12 years and over, only if:

- the severity of the condition is assessed objectively, for example, using a weekly urticaria activity score of 28 or more,
- the patient's condition has not responded to standard treatment with H₁-antihistamines and leukotriene receptor antagonists,
- omalizumab is stopped at or before the fourth dose if the condition has not responded,
- omalizumab is stopped at the end of a course of treatment (6 doses) if the condition has responded and is restarted only if the condition relapses,
- omalizumab is administered under the management of a secondary care specialist in dermatology, immunology or allergy,
- the manufacturer provides omalizumab with the discount agreed in the patient access scheme.

Patients currently receiving omalizumab whose disease does not meet the above criteria should have the option to continue treatment until they and their clinician consider it appropriate to stop.

www.nice.org.uk/TA339

Scottish Medicines Consortium (SMC) decisions

The *Scottish Medicines Consortium* has advised (December 2014) that omalizumab (*Xolair*[®]) is accepted for restricted use within NHS Scotland for the treatment of chronic spontaneous urticaria in patients aged 12 years and over, who have had an inadequate response to combination therapy with H₁-antihistamines, leukotriene receptor antagonists and H₂-antihistamines, used according to current treatment guidelines.

- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug.

Solution for injection

▶ **Xolair** (Novartis Pharmaceuticals UK Ltd)

Omalizumab 150 mg per 1 ml Xolair 150mg/1ml solution for injection pre-filled syringes | 1 pre-filled disposable injection [PoM] £256.15

Xolair 75mg/0.5ml solution for injection pre-filled syringes | 1 pre-filled disposable injection [PoM] £128.07

LEUKOTRIENE RECEPTOR ANTAGONISTS

Leukotriene receptor antagonists

29-Nov-2017

Overview

The leukotriene receptor antagonist montelukast below blocks the effects of cysteinyl leukotrienes in the airways.

Montelukast has not been shown to be more effective than a standard dose of inhaled corticosteroid, but the two drugs appear to have an additive effect. The leukotriene receptor antagonists may be of benefit in exercise-induced asthma and in those with concomitant rhinitis, but they are less effective in children with severe asthma who are also receiving high doses of other drugs.

There is some limited evidence to support the intermittent use of montelukast in children under 12 years with episodic wheeze associated with viral infections [unlicensed use]. Treatment is started at the onset of either asthma symptoms

or of coryzal symptoms and continued for 7 days; there is no evidence to support this use in moderate or severe asthma.

Montelukast

• **INDICATIONS AND DOSE**

Prophylaxis of asthma

▶ BY MOUTH

- ▶ Child 6 months–5 years: 4 mg once daily, dose to be taken in the evening
- ▶ Child 6–14 years: 5 mg once daily, dose to be taken in the evening
- ▶ Child 15–17 years: 10 mg once daily, dose to be taken in the evening

Symptomatic relief of seasonal allergic rhinitis in patients with asthma.

▶ BY MOUTH

- ▶ Child 15–17 years: 10 mg once daily, dose to be taken in the evening

- **INTERACTIONS** → Appendix 1: montelukast

• **SIDE-EFFECTS**

- ▶ **Common or very common** Diarrhoea · fever · gastrointestinal discomfort · headache · nausea · skin reactions · upper respiratory tract infection · vomiting
- ▶ **Uncommon** Akathisia · anxiety · arthralgia · asthenia · behaviour abnormal · depression · dizziness · drowsiness · dry mouth · haemorrhage · irritability · malaise · muscle complaints · oedema · seizure · sensation abnormal · sleep disorders

- ▶ **Rare or very rare** Angioedema · concentration impaired · disorientation · eosinophilic granulomatosis with polyangiitis · erythema nodosum · hallucination · hepatic disorders · memory loss · palpitations · pulmonary eosinophilia · suicidal tendencies · tremor

SIDE-EFFECTS, FURTHER INFORMATION Eosinophilic granulomatosis with polyangiitis (Churg-Strauss syndrome) has occurred very rarely in association with the use of montelukast; in many of the reported cases the reaction followed the reduction or withdrawal of oral corticosteroid therapy. Prescribers should be alert to the development of eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, or peripheral neuropathy.

- **PREGNANCY** Manufacturer advises avoid unless essential. There is limited evidence for the safe use of montelukast during pregnancy; however, it can be taken as normal in women who have shown a significant improvement in asthma not achievable with other drugs before becoming pregnant.

- **BREAST FEEDING** Manufacturer advises avoid unless essential.

- **DIRECTIONS FOR ADMINISTRATION** Granules may be swallowed or mixed with cold, soft food (not liquid) and taken immediately.

- **PRESCRIBING AND DISPENSING INFORMATION** Flavours of chewable tablet formulations may include cherry.

- **PATIENT AND CARER ADVICE** Patients or carers should be given advice on how to administer montelukast granules. Medicines for Children leaflet: Montelukast for asthma www.medicinesforchildren.org.uk/montelukast-asthma

• **NATIONAL FUNDING/ACCESS DECISIONS**
SINGULAIR[®] GRANULES

Scottish Medicines Consortium (SMC) decisions

The *Scottish Medicines Consortium* has advised (June 2007) that *Singulair*[®] granules are restricted for use as an alternative to low-dose inhaled corticosteroids for children 2–14 years with mild persistent asthma who have not recently had serious asthma attacks that required oral