

**Montelukast paediatric 4mg granules
(Singulair[®])**

(No. 111/04)

Merck Sharp & Dohme Ltd

9 August 2004

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and advises NHS Boards and ADTCs on its use in NHS Scotland. The advice is summarised as follows:

ADVICE: following an abbreviated submission

Montelukast paediatric 4 mg granules (Singulair[®]) are accepted for use in NHS in Scotland for the treatment of asthma as add-on therapy in those patients with mild to moderate persistent asthma who are inadequately controlled on inhaled corticosteroids and in whom 'as needed' short-acting beta-agonists provide inadequate clinical control of asthma. It is also accepted for the prophylaxis of asthma in which the predominant component is exercise-induced bronchoconstriction.

This formulation is suitable for the treatment of children aged 6 months to 5 years, and the licence for montelukast has been extended to include children aged 6 months to 2 years, though the Summary of Product Characteristics adds that experience in those aged 6 to 12 months is limited. Its introduction is expected to have minimal resource implications in Scotland.

D H Lawson
Chairman