

Product Update:

rufinamide 40mg/mL oral suspension (Inovelon®)

(No: 795/12)

Eisai Ltd

08 June 2012

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

ADVICE: following an abbreviated submission

rufinamide 40mg/mL oral suspension (Inovelon®) is accepted for restricted use within NHS Scotland.

Indication under review: adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 4 years of age or older.

SMC restriction: restricted to use in patients who have failed treatment with or are intolerant of other antiepileptic drugs.

Adjunctive rufinamide significantly reduced the frequency of total seizures and tonic-atonic seizures and significantly improved seizure severity when compared to placebo in patients with LGS. The oral suspension is bioequivalent to the tablets and provides an alternative formulation for patients who have difficulty swallowing. Depending on the dose it may be more expensive than the tablets but any overall budget impact is likely to be small.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after evaluation of the evidence submitted by the company. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

This assessment is based on data submitted by the applicant company up to and including 29 March 2012.

**Chairman,
Scottish Medicines Consortium**