www.scottishmedicines.org.uk

Healthcare Improvement Scotland | SMC Advice on new medicines

Product update
SMC2146

rufinamide 40mg/mL oral suspension and 100mg, 200mg, 400mg tablets (Inovelon®)

Eisai Limited

8 March 2019

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 NHSScotland. The advice is summarised as follows:

ADVICE: following an abbreviated submission

rufinamide (Inovelon®) is accepted for restricted use within NHSScotland.

Indication under review: as adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome in patients 1 years to <4 years.

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

Rufinamide (Inovelon®) has previously been accepted for restricted use in adults and children aged ≥4 years. The licence has been extended to include children aged 1 year to <4 years.

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 careful consideration and evaluation of the available evidence. 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.

Published 08 April 2019

This assessment is based on data submitted by the applicant company up to and including 29 January 2019.

Chairman
Scottish Medicines Consortium

Published 08 April 2019