

Product Update:

deferasirox 90mg, 180mg and 360mg film-coated tablets (Exjade®)
SMC No (1246/17)

Novartis Pharmaceuticals UK Limited

05 May 2017

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

deferasirox film-coated tablets (Exjade®) is accepted for restricted use within NHS Scotland.

Indication under review:

- Treatment of chronic iron overload due to frequent blood transfusions ($\geq 7\text{mL/kg/month}$ of packed red blood cells) in patients with beta thalassaemia major aged 6 years and older.
- Treatment of chronic iron overload due to blood transfusions when deferoxamine therapy is contraindicated or inadequate in the following patient groups:
 - in paediatric patients with beta thalassaemia major with iron overload due to frequent blood transfusions ($\geq 7\text{mL/kg/month}$ of packed red blood cells) aged 2 to 5 years,
 - in adult and paediatric patients with beta thalassaemia major with iron overload due to infrequent blood transfusions ($< 7\text{mL/kg/month}$ of packed red blood cells) aged 2 years and older,
 - in adult and paediatric patients with other anaemias aged 2 years and older.

SMC restriction: deferasirox film-coated tablets are restricted to use as for the SMC advice issued for deferasirox dispersible tablets ([No.347/07](#)).

Deferasirox dispersible tablets were accepted for restricted use following a resubmission under the ultra-orphan process ([No. 347/07](#)).

Deferasirox film-coated tablets will replace deferasirox dispersible tablets which are to be discontinued. Deferasirox film-coated tablets demonstrated higher bioavailability compared to the deferasirox dispersible tablet formulation and therefore a dose adjustment is required when switching from dispersible tablets to film-coated tablets.

Deferasirox film-coated tablets cannot be accepted for use in treatment of chronic iron overload requiring chelation therapy when deferoxamine therapy is contraindicated or inadequate in patients with non-transfusion-dependent thalassaemia syndromes aged 10 years and older as a full submission has not been received by SMC for this indication.

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 13 March 2017.

**Chairman
Scottish Medicines Consortium**