



Final Appraisal Recommendation

Advice No: 2816 – October 2016

Insulin degludec (Tresiba®) 100 units/ml and 200 units/ml solution for injection in prefilled pen (FlexTouch®) or 100 units/ml solution for injection in cartridge (Penfill®)

Resubmission by Novo Nordisk Ltd

Recommendation of AWMSG

Insulin degludec (Tresiba®) is recommended as an option for restricted use within NHS Wales for the treatment of diabetes mellitus in adult patients where treatment with a basal insulin analogue is considered appropriate.

Insulin degludec (Tresiba®) is not recommended for use within NHS Wales for the treatment of diabetes mellitus in adolescents and children from the age of 1 year.

Additional note(s):

- Please refer to the Summary of Product Characteristics for the full licensed indication.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 3158), which includes the AWMSG Secretariat Assessment Report (ASAR), the Preliminary Appraisal Recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.

This recommendation has been ratified by Welsh Government and will be considered for review every three years.

Marketing authorisation holder on first issue	Novo Nordisk Ltd
Date of first issue	October 2016
Last reviewed	August 2020

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