Norwegian Medicines Agency

Merck Sharp & Dohme Ltd
Hertford Road, Hoddesdon
EN11 9BU Hertfordshire
Storbritannia

Your ref.:	Date:	Our ref.:	Officer:
	9 April 2018	17/01893-43	Nina Malvik

MARKETING AUTHORISATION

Steglatro, ertugliflozin «Merck Sharp & Dohme», MA no. EU/1/18/1267

According to the Norwegian Medicinal Product Regulation (forskrift om legemidler 18. desember 2009 nr. 1839) § 6-1 the Norwegian Medicines Agency hereby grants marketing authorisation for the above mentioned medicinal product issued in accordance with the Commission Decision C(2018)1903 of 21.03.2018.

The marketing authorisation is granted 21.03.2018. In accordance with the Norwegian Medicinal Product Regulation § 6-1 the marketing authorisation is valid until 21.03.2023.

Conditions for the marketing authorisation are set in:
- Annex II of the product information
- Prescription category: C.

This marketing authorisation gives the holder the right to market the above mentioned medicinal product in Norway in accordance with the authorisation and relevant legislation in force.

Application for renewal of the marketing authorisation must be submitted to The European Medicines Agency no later than 9 months prior to the expiry date of the marketing authorisation, according to the Norwegian Medicinal Product Regulation § 6-2.

Yours sincerely
Norwegian Medicines Agency

Elin S. Sanne (b.a.)
Senior Adviser
Safe use

This document is electronically approved and sent without signature.

Attachments: General information on marketing authorisations

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Letters should be addressed to the Norwegian Medicines Agency.
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