



European Medicines Agency

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**Public Statement on the expiry and withdrawal of the marketing authorisation
in the European Union for**

**Trazec
*nateglinide***

On 3 April 2001, the European Commission granted a marketing authorisation valid throughout the European Union (EU) for the medicinal product Trazec (nateglinide), indicated for combination therapy with metformin in type 2 diabetic patients inadequately controlled despite a maximally tolerated dose of metformin alone.

Trazec (nateglinide) had not been marketed in Europe since this initial marketing authorisation. In accordance with article 14(4) of Regulation (EC) No 726/2004 ('sunset clause'), the marketing authorisation of a medicinal product lapses if the product has never been marketed in one of the Member States within three years of its initial authorisation, calculated from the entry into force of the Regulation (20 November 2005) for products authorised before this date.

Because of this, from 20 November 2008, the marketing authorisation for Trazec is no longer valid.

Starlix (nateglinide) is an identical product authorised in the EU.

Pursuant to the expiry of the marketing authorisation, the European Assessment Report (EPAR) for Trazec will be updated to reflect that the marketing authorisation is no longer valid.

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