26 February 2015
EMA/CHMP/124102/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Toujeo[2]

insulin glargine 300 units/ml

On 26 February 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a group of variations to the terms of the marketing authorisation for the medicinal product Optisulin. The marketing authorisation holder for this medicinal product is Sanofi-Aventis Deutschland GmbH. They may request a reexamination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a group of variations recommending the addition of a new formulation to the marketing authorisation of the medicinal product Optisulin and a change of the invented name to Toujeo. The new formulation of Toujeo is a higher strength insulin (300 U/ml).

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

The active substance of Toujeo is insulin glargine, a long acting insulin analogue (ATC code: A10A E04). Insulin glargine was first authorised as a 100 U/ml formulation as Lantus and Optisulin in the EU in June 2000. Insulin glargine binds specifically to the human insulin receptor and results in the same pharmacological effects as human insulin.

The benefit with Toujeo is its ability to lower high blood glucose. The most common side effects are hypoglycaemia, skin changes and injection site reactions. In Type 2 diabetes patients, the incidence of confirmed hypoglycaemia was lower with Toujeo, in particular at night, as compared to insulin glargine 100 U/ml.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.
[2] Previously known as Optisulin.

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Insulin glargine 100 U/ml and Toujeo are not bioequivalent and are not directly interchangeable. Therefore, when switching from insulin glargine 100 U/ml to Toujeo, this can be done on a unit to unit basis, but a higher Toujeo dose (approx. 10-18%) may be needed to achieve target ranges for plasma glucose levels. When switching from Toujeo to insulin glargine 100 U/ml, the dose should be reduced (approx. by 20%) to reduce the risk of hypoglycaemia.

A pharmacovigilance plan for Toujeo will be implemented as part of the marketing authorisation.