Saudi Public Assessment Report

(Clinical Summary Report)

Tresiba® FlexTouch®

Type of Application: Variation Application (New Therapeutic Indication).

Type of Product: Biological Drug.

Active Pharmaceutical Ingredient(s): Insulin Degludec

ATC code: A10AE06.

Dosage Form: Solution for injection in pre-filled pen.

Dosage Strength: 100 IU/ml.

Pack Size: 5 pre-filled pens x 3ml.

Shelf life: 30 Months.

Storage Conditions: Store in a refrigerator (2°c – 8°c).

Reference Product in SA (if applicable): NA.

Marketing Authorization Holder: NOVO NORDISK.

Manufacturer: NOVO NORDISK.

Registration No.: 67-100-15.

Decision and Decision Date: Approved on 4/04/2015.

Proposed Indications: Fertility, pregnancy and lactation: The treatment with Tresiba may be considered during pregnancy if clinically needed.

Product Background

This application is considered a Type II Variation for tresiba. .Tresiba is a biologic product for Saudi regulatory purposes. Furthermore, this application is qualified to follow the SFDA's normal submission regulatory pathway.

The SFDA approval for the submitted variation is based on a review of the safety and efficacy as summarized hereinafter:

Clinical Aspects

The clinical development program for Tresiba® FlexTouch® in pregnant subjects consisted of one clinical study (maternal safety and pregnancy outcome trial): NN1250-4300 efficacy and safety of insulin degludec versus insulin detemir, both in combination with insulin aspart among pregnant women with type 1 diabetes (EXPECT trial).

Summary of the clinical studies presented hereafter:

- NN1250-4300 (EXPECT trial): This was a multinational, multicenter, randomized (1:1), open-label, parallel-group, treat-to-target, active-controlled phase 3b trial comparing the effect on glycemic control of insulin degludec (IDeg) once daily plus insulin aspart (IAsp) 2-4 times daily with meals and insulin detemir (IDet) once daily or twice daily plus insulin aspart (IAsp) 2-4 times daily with meals in a population of women with T1DM randomized either non-pregnant with the intention to become pregnant or pregnant from GW 8-13 + 6 days. The primary efficacy endpoint was the last planned HbA1c prior to delivery after gestational week (GW) 16. A total of 306 women with T1DM were planned to be screened of which 214 women were planned to be randomized to either IDeg + IAsp treatment group or IDet + IAsp treatment group.

The clinical pharmacology, efficacy and safety results from the aforementioned study were assessed by the SFDA efficacy and safety department. Based on the review of the submitted evidence, the benefit/risk balance of Tresiba® FlexTouch® is considered positive. Therefore, we recommend the approval of the variation to the marketing authorization of Tresiba® FlexTouch® .

Product Information

The approved Summary of Product Characteristics (SPC) with the submission can be found in Saudi Drug Information System (SDI) at: https://sdi.sfda.gov.sa/

The date of revision of this text corresponds to that of the Saudi PAR. New information concerning the authorized medicinal product in question will not be incorporated into the Saudi PAR. New findings that could impair the medicinal product's quality, efficacy, or safety are recorded and published at (SDI or Summary Saudi-PAR report).

For inquiry and feedback regarding Saudi PAR, please contact us at Saudi.PAR@sdfa.gov.sa