

IMPORTANT INFORMATION NOTE AGREED WITH THE ITALIAN MEDICINES AGENCY (AIFA)

Rome, 01 August 2023

Tresiba® (Insulin degludec)

Shortage of the medicine Tresiba® (Insulin degludec) 100 U/ML - solution for injection - subcutaneous use - pre-filled pen (glass) (FlexTouch®) - 3 ml - 5 pre-filled pens (A.I.C. 042658029)

Dear Doctor,

The Italian Medicines Agency, in agreement with Novo Nordisk SpA, legal representative in Italy of Novo Nordisk A/S, intends to inform you about the following:

Summary and information context:

1. Tresiba® FlexTouch® 100 U/ML 5 pre-filled pens (A.I.C. 042658029) is a long-acting basal insulin indicated for the treatment of diabetes mellitus in adults, adolescents and children from 1 year of age.
2. Currently, the supply of the medicinal product Tresiba® FlexTouch® 100 U/ML 5 pre-filled pens (A.I.C. 042658029) is intermittent due to a reduced production capacity of the holder.
3. It is estimated that the supply of Tresiba® FlexTouch® 100 U/ML 5 pre-filled pens (A.I.C. 042658029), could be intermittent for the entire year 2023. Although supply continues to increase, it is not possible to estimate with certainty when it will be sufficient to fully meet current demand. At the moment, a period of discontinuous supplies from 11 July until 20 August 2023 is confirmed. The shortage of supply is not related to any defect in the quality of the medicine or safety concerns.

For any update on the shortage status, please refer to the List of Medicines in shortage, updated periodically and published at the following link: <https://www.aifa.gov.it/farmaci-attualmente-carenti>

4. Due to discontinuous supplies, patients may not find the medicinal product and, consequently, may not be able to comply with the prescribed therapeutic plan, with possible serious consequences for their health, specifically hyperglycemia, which can lead to diabetic ketoacidosis.

Mitigation actions

1. We inform you that, with the authorization of AIFA, Novo Nordisk SpA has imported multilingual Algerian/French packs of Tresiba FlexTouch® with 1 pre-filled pen, "Tresiba® (*Insuline degludec*) 100 unités/ml- solution injectable en stylo prérempli (FlexTouch®) 1 x 3 ml – utilisation sous-cutanée", which from a qualitative-quantitative point of view are identical to the medicine marketed in Italy. To facilitate supply, imported Tresiba® FlexTouch® packs of 1 pre-filled pen will be distributed either in the imported package, containing 1 pre-filled pen, or in a box of 5 single packs. Imported foreign packages will be distributed with an enclosed package leaflet in Italian in case it becomes necessary to supplement the availability of packages in Italian packaging.
2. We therefore ask for your kind support in ensuring, during this period of shortage, the prescription to each patient of the number of packs of Tresiba® FlexTouch® 100 U/ML strictly necessary for the

continuation of therapy, to avoid hoarding phenomena and thus guarantee all patients access to therapy.

3. We ask for your kind support to ensure that patients are made aware of the above and in case of unavailability of the medicine Tresiba® FlexTouch® 100 U/ML pre-filled pens, they are transferred to appropriate alternative treatments.

Call for reporting

Adverse events, including treatment errors, related to Tresiba® FlexTouch® 100 U/ML 5 pre-filled pens (AIC 042658029) or any other Novo Nordisk product should be reported to Novo Nordisk S.p. A. and the Italian Medicines Agency via the following link <https://www.aifa.gov.it/web/guest/content/segnalazioni-reazioni-avverse>.

AIFA takes this opportunity to remind all Healthcare Professionals of the importance of reporting suspected adverse drug reactions, as an indispensable tool to confirm a favorable risk-benefit ratio in real conditions of use.

Reports of Suspected Adverse Reaction from medicinal products must be sent to the Pharmacovigilance Responsible of the operator's facility.

This Information Note is also published on the AIFA website (www.agenziafarmaco.it) whose regular consultation is recommended for the best professional information and service to the citizen.

Company contacts

Further information on drug shortages and medical information can be obtained by contacting Novo Nordisk S.p.A, Via Elio Vittorini 129, 00144 Rome, Italy- +39 06 500881- Website <https://www.novonordisk.it/>

Novo Nordisk S.p.A will continue to provide AIFA with updates on the supply situation as soon as new information becomes available.

Novo Nordisk is working assiduously to solve these temporary problems.

We sincerely apologize for this unfortunate situation and for the concerns and inconvenience it may cause.