



For healthcare professionals only

1

*Safe guard
their Journey*

EDA ASSESSMENT REPORT FOR GLARGIVIN® 1

1. General introduction about the product including brief description of the AI, its mode of action and indications

Glarginin Solution for Injection is a **second brand** product developed by Eva Pharma for Pharmaceutical Industries (2) for **reference product Abasaglar** solution for injection, **Eli Lilly**. The active ingredient of the product is Insulin Glargine (recombinant DNA origin); Insulin glargine is a modified form of human insulin to treat adults and children with type 1 diabetes and adults with type 2 diabetes to improve and maintain glycemic control. Insulin glargine is a long-acting insulin injected once daily and provided a basal insulin level throughout the day. They are used in one fill volume 3 ml Cartridges.

The pharmaceutical development of this product was straight forward depending on the data provided by Eli Lilly

• **Product specification:**

-The specifications proposed for **release and stability testing of glarginin** finished product comply with Ph. Eur. and in-house based on Eli Lilly

- **Pharmaceutical Development** **Components of drug product**

The excipients used in **Glarginin** Solution for Injection are Metacresol, Glycerin Zinc oxide, Hydrochloric acid, Sodium hydroxide and Water for Injections. The excipients used in the development of formulation are present in the reference product **Abasaglar** solution for injection, Eli Lilly.

- **Formulation Development**

The composition of the drug product was selected to match exactly the formulation of the reference products Quantitatively and Qualitatively. No own formulation development was performed but followed the reference product formulation.

As a second brand for **Abasaglar 100IU**, the **comparability study** was reviewed according to ICH* Q5E & successfully demonstrated that there is **no statistically significant difference between Abasaglar and Glarginin** Solution for Injection.

Therapeutic indications

Treatment of diabetes mellitus in adults, adolescents and children aged 2 years

Contraindications

Hypersensitivity to the active substance or to any of the excipients listed.

Special warnings and precautions for use **TRACEABILITY**

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

DIABETIC KETOACIDOSIS

GLARGIVIN® is not the insulin of choice for the treatment of diabetic ketoacidosis. Instead, regular insulin administered intravenously is recommended in such cases.

Fertility, pregnancy and lactation

Pregnancy

For insulin glargine no clinical data on exposed pregnancies from controlled clinical studies

are available. A large amount of data

on pregnant women (more than 1,000 pregnancy outcomes) indicate no specific adverse effects of insulin glargine on pregnancy and no specific malformative nor feto/neonatal toxicity of insulin glargine.

Animal data do not indicate reproductive toxicity.

The use of GLARGIVIN® may be considered during pregnancy, if clinically needed.

Breast-feeding

It is unknown whether insulin glargine is excreted in human milk. No metabolic effects of ingested insulin glargine on the breast-fed newborn/infant are anticipated since insulin glargine as a peptide is digested into amino acids in the human gastrointestinal tract. Breast-feeding women may require adjustments in insulin dose and diet.

Fertility

Animal studies do not indicate direct harmful effects with respect to fertility.

1- Glarginin-QF:BioInn.005.04 Issue/Rev. no: 7/0 Issue date: 25/12/2022

*ICH: International Conference on Harmonization

Egyptian Drug Authority Glarginin approved insert leaflet 29/9/2024.

Always read the full prescribing information.

Healthcare professionals are asked to report any suspected adverse reactions to Egyptian Pharmacovigilance Centre e-mail: pv.followup@edaegypt.gov.eg or Egyptian Drug Authority (EDA) website: <https://www.edaegypt.gov.eg> or (EPVC) [hotline 15301].



For more information please contact:

EVA Pharma for Pharmaceuticals & Medical Appliances – Egypt
Factory & Scientific office: 176 El Sadat St., Pyramids, Giza, Egypt
Telephone: (+202) 239 92761 **Fax:** (+202) 239192782
pv.report@evapharma.com www.evapharma.com