Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

GlucaGen Hypokit 1 mg powder and solvent for solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance: Human glucagon produced in Saccharomyces cerevisiae by recombinant DNA technology. One vial contains 1 mg glucagon as hydrochloride corresponding to 1 mg (1 IU) glucagon/ml after reconstitution. For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Powder and solvent for solution for injection.

Product imported fromtheCzech Republic, Poland and the United Kingdom: Before reconstitution the powder should be white or nearly white powder. The solvent should be clear and colourless without particles.

4 CLINICAL PARTICULARS

As per PA0218/031/002.

5 PHARMACOLOGICAL PROPERTIES

As per PA0218/031/002.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Hydrochloric acid for pH adjustment
Sodium hydroxide for pH adjustment
Water for injections

The reconstituted solution contains glucagon 1 mg/ml and lactose monohydrate 107 mg/ml.

6.2 Incompatibilities

There are no known incompatibilities with GlucaGen.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the container and outer package of the product on the market in the country of origin.

The reconstituted GlucaGen should be used immediately after preparation.

6.4 Special precautions for storage

GlucaGen HypoKit should be stored at a temperature of 2-8°C (in a refrigerator). The user can store GlucaGen HypoKit at a temperature not exceeding 25ºC for 18 months provided that the expiry date is not exceeded. Store in the original package in order to protect from light.

Do not freeze.

If in rare cases, the reconstituted product shows any signs of fibril formation (viscous appearance) or insoluble matter it should be discarded.

6.5 Nature and contents of container

Container for GlucaGen:
Vial made of glass closed with a bromobutyl stopper and covered with an aluminium cap.

Container for solvent:
Pre-filled syringe with plunger (bromobutyl rubber) and needle.

The vial is provided with a tamper-proof plastic cap which must be removed before use.
The components are contained in an orange coloured plastic container

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Reconstitution: Inject the water for injections (1.1 ml) into the vial containing the freeze-dried glucagon. Shake the vial gently until the glucagon is completely dissolved and the solution is clear. Withdraw the solution back into the syringe. Note that a syringe with a thinner needle and a finer graduation may be more suitable for use in diagnostic procedures. The reconstituted solution appears clear and colourless and forms an injection of 1 mg (1 IU) per ml to be administered subcutaneously, intramuscularly or intravenously

Any unused product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/331/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th October 2014

10 DATE OF REVISION OF THE TEXT

December 2019