

Prescribing Information

GlucaGen® HypoKit 1mg

Glucagon (rDNA).

Presentation: A vial containing 1 mg (1 IU) glucagon, rDNA, as the hydrochloride, and lactose 107 mg, together with a pre-filled syringe containing 1.1 ml Water for Injections.

Indications: Treatment of severe hypoglycaemic reactions which may occur in the management of insulin treated persons with diabetes mellitus. Motility inhibition in examinations of the gastrointestinal tract.

Posology and administration: The glucagon is dissolved in the accompanying solvent before use.

Therapeutic indication (severe hypoglycaemia): 1 mg (adults, children above 25 kg or older than 6 - 8 years) or 0.5 mg (children below 25 kg or younger than 6 - 8 years) by subcutaneous or intramuscular injection. When the patient responds, administer oral carbohydrate. If no response within 10 minutes, give intravenous glucose.

Diagnostic indication: Doses range from 0.2 - 2 mg depending on the diagnostic technique used and the route of administration. Usual dose for relaxation of stomach, duodenal bulb, duodenum and small bowel is 0.2 - 0.5 mg i.v. or 1 mg i.m. To relax the colon 0.5 - 0.75 mg i.v. or 2 mg i.m. Give oral carbohydrate after the end of the diagnostic procedure if compatible with the procedure applied.

Contraindications:

Phaeochromocytoma. Hypersensitivity to glucagon or lactose.

Special warnings and precautions for use:

Therapeutic indication: Give oral carbohydrate when the patient has responded to treatment to prevent relapse of hypoglycaemia.

Diagnostic indication: Discomfort may be experienced in connection with diagnostic procedures particularly if the person has been fasting. Give oral carbohydrate to patients who have been fasting after the end of a diagnostic procedure, if this is compatible with the procedure applied. If fasting is needed post-examination or in case of severe hypoglycaemia, i.v. glucose may be required. Glucagon reacts antagonistically towards insulin. Observe caution in patients with insulinoma or glucagonoma, and in diabetic patients or elderly patients with known cardiovascular disease. Do not give in i.v. infusion.

Fertility, pregnancy and lactation: Glucagon does not cross the placenta. Glucagon has been used in pregnant diabetics; no harmful effects known with respect to course of pregnancy or health of foetus and neonate. Use during lactation for the treatment of severe hypoglycaemia will not have any effect on the child.

Undesirable effects: Therapeutic indication: Common: nausea; uncommon: vomiting; rare: abdominal pain; very rare: hypersensitivity reactions including anaphylactic reaction/shock.

Diagnostic indication: Common: nausea; uncommon: hypoglycaemia, vomiting; rare: abdominal pain; very rare: hypoglycaemic coma, bradycardia, tachycardia, hypotension, hypertension hypersensitivity reactions including anaphylactic reaction/shock. The Summary of Product Characteristics should be consulted for a full list of side effects.

MA numbers and Basic NHS Price: GlucaGen® HypoKit 1 mg PL 4668/0027 PL 4668/0028 £11.52.

Legal category: POM.

Full prescribing information can be obtained from:

Novo Nordisk Limited, Broadfield Park, Brighton Road, Crawley, West Sussex, RH11 9RT.

Marketing Authorisation Holder: Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd, Denmark.

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novo Nordisk Limited (Telephone Novo Nordisk Customer Care Centre 0845 6005055). Calls may be monitored for training purposes.

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