Hypurin® Bovine and Porcine Insulin Prescribing Information

Please read the Summary of Product Characteristics before prescribing.

PRESENTATION:

Vials and cartridges containing Crystalline Insulin Ph Eur (Bovine) 100IU/ml or Crystalline Insulin Ph Eur (Porcine) 100IU/ml

INDICATION:

Treatment of insulin dependent diabetes mellitus.

DOSAGE AND ADMINISTRATION:

To be determined by physician according to patient needs. Usually administered subcutaneously but where necessary may be given intramuscularly (onset is more rapid and overall duration shorter).

CONTRAINDICATIONS:

Hypoglycaemia. Hypersensitivity to insulin or excipients.

SPECIAL WARNINGS AND PRECAUTIONS:

Must not be given intravenously. Susceptibility to hypoglycaemia may be increased by an inaccurate or excessive dosage, omission of a meal or increased physical activity. Blood or urinary glucose concentrations should be monitored and the urine tested for ketones by patients. Newly diagnosed patients may experience fluctuating insulin requirements during first weeks, months or even years of treatment. Patients transferred to Hypurin® insulins from other preparations may require dosage adjustments. Warning symptoms of hypoglycaemia may be changed, less pronounced or absent in certain risk groups (consult SmPC). Elderly are more susceptible to episodes of severe, rapid onset hypoglycaemia. Cardiac failure reported when thiazolidinediones are used in combination with insulin. Insulin requirements may increase during illness, puberty or emotional upset. Insulin resistance is frequently associated with lipid disorders, hypertension and ischaemic heart disease. Insulin requirements may decrease with liver disease, disease of the adrenal, pituitary or thyroid glands and coeliac disease. In patients with severe renal impairment, insulin requirements may fall and dosage reduction may be necessary. The compensatory response to hypoglycaemia may also be impaired. Insulin requirements may be increased in the premenstrual period but may be reduced during or after a menstrual cycle. Insulin requirements are usually reduced but occasionally increased during periods of increased activity. Increase in subcutaneous blood flow, e.g. with a hot bath, sunbathing/sunbed or sauna may increase rate of absorption of insulin and increase risk of hypoglycaemia.

INTERACTIONS;

Increased insulin requirement with chloropromazine, corticosteroids, diazoxide, thiazide or loop diuretics sympathomimetic agents, thyroid hormone replacement therapy, smoking. Decreased insulin requirement with ACE inhibitors, alcohol, anabolic steroids, NSAIDS or salicylates, testosterone, disopyramide, quinidine, MAOIs, fluoxetine, amitriptyline, guanethidine, chloroquine, quinine, fenfluramine, octreotide, fibrates, mebendazole, and tetracyclines. Hypoglycaemic activity may be potentiated by concomitant administration of high-dose pentoxifylline injection. For further interactions consult SmPC.

PREGNANCY AND LACTATION:

Pregnancy: Insulin requirements may vary during pregnancy and should be assessed frequently. Lactation: Caution.

SIDE EFFECTS:

Hypoglycaemia, hypokalaemia, weight gain, lipodystrophy at injection site, insulin hypersensitivity, neuropathic pain, allergic reactions to zinc, protamine or excipients, local allergic reactions to insulin (e.g. pruritus, erythema and oedema), urticaria, rash, nausea, dyspnoea or wheezing. Rare: anaphylaxis, angioedema.

LEGAL CATEGORY: POM

PACKAGE QUANTITY AND PRICE:

Hypurin Porcine Neutral, Isophane or 30/70 Mix: 10ml vials: £34.43; 3ml cartridges (5 pack): £51.64 Hypurin Bovine Neutral: 10ml vials: £27.72; Hypurin Bovine Protamine Zinc: 10ml vials: £27.72

MARKETING AUTHORISATION NUMBERS: Hypurin Bovine Neutral: vials PL29831/0125, Hypurin Bovine Protamine Zinc: vials PL29831/0128, Hypurin Porcine Neutral: vials PL29831/0126, cartridges PL29831/0124: Hypurin Porcine Isophane: vials PL29831/0121, cartridges PL29831/0122: Hypurin Porcine 30/70 Mix: vials PL29831/0118, cartridges PL29831/0119

MARKETING AUTHORISATION HOLDER:

Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

DATE OF LAST REVISION: May 2019

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 the Drug Safety and Information Department at Wockhardt UK (Tel: 01978 661261).

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