

Hypurin® Porcine Insulin Range Prescribing Information

Please read the Summary of Product Characteristics before prescribing.

PRESENTATION: Vials and cartridges containing Crystalline Insulin Ph Eur (Porcine) 100 IU/ml

INDICATION: Treatment of insulin dependent diabetes mellitus.

DOSAGE AND ADMINISTRATION: To be determined by physician according to patient needs. Usually administered subcutaneously. May be given intramuscularly (onset is more rapid and overall duration shorter). Neutral formulation may be given intravenously. Isophane and 30/70 mix formulations **MUST NOT** be given intravenously.

CONTRAINDICATIONS: Hypoglycaemia. Hypersensitivity to insulin or excipients.

SPECIAL WARNINGS AND PRECAUTIONS: Isophane and 30/70 mix formulations must not be given intravenously. Susceptibility to hypoglycaemia may be increased by 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 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 chlorpromazine, 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. Insulin requirements may be increased or decreased with clonidine, beta blockers, Ca channel blockers, cyclophosphamide, isoniazid, gemfibrozil and oral contraceptives.

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: 10 ml vials: £25.20; 3 ml cartridges (5 pack): £37.80

MARKETING AUTHORISATION NUMBERS: Hypurin Porcine Neutral: vials 29831/0126, cartridges 29831/0124; Hypurin Porcine Isophane: vials 29831/0121, cartridges 29831/0122; Hypurin Porcine 30/70 Mix: vials 29831/0118, cartridges 29831/0119

MARKETING AUTHORISATION HOLDER: Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

DATE OF LAST REVISION: November 2019

N.B. The following text should also be included (in a slightly larger font size) within a box at the end of the PI:

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).

When printed, the PI must be compliant with the APBI code of practice, i.e. lower case "x" should be at least 1mm in height and no more than 100 characters per line.