**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. Hypurin® Porcine Isophane in cartridges is only suitable for subcutaneous injections from a reusable pen. If administration by syringe is necessary, a vial should be used.

**CONTRAINDICATIONS:** Hypoglycaemia. Hypersensitivity to insulin or excipients.

**SPECIAL WARNINGS AND PRECAUTIONS:** Isophane and 30/70 mix formulations must not be given intravenously under any circumstances. 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 including those in whom glycaemic control is greatly improved, e.g. by intensified insulin therapy, with a long history of diabetes, who are elderly, receiving concomitant treatment with certain medicinal products e.g. beta blockers or clonidine, who have experienced repeated episodes of hypoglycaemia. Elderly are more susceptible to episodes of severe, rapid onset hypoglycaemia. Combination with pioglitazone: cases of cardiac failure have been reported when thiazolidinediones are used in combination with insulin, especially in patients with risk factors for development of cardiac heart failure. If the combination is used, patients should be observed for signs and symptoms of heart failure, weight gain and oedema. Pioglitazone should be discontinued if any deterioration in cardiac symptoms occurs. Insulin requirements may increase during illness (including infection and trauma), 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. Patients must perform continuous rotation of the injection site to reduce the risk of developing lipodystrophy and cutaneous amyloidosis. There is a potential risk of delayed insulin absorption and worsened glycaemic control following insulin injections at sites with these reactions. A sudden change in the injection site to an unaffected area may result in hypoglycaemia. Blood glucose monitoring is recommended after the change in the injection site, and dose adjustment of antidiabetic medications may be considered.

**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. Insulin requirements may be increased or decreased with clonidine, beta blockers, Ca channel blockers, cyclophosphamide, isoniazid, gemfibrozil and oral contraceptives. Thiazolidinediones may induce oedema and/or heart failure with higher rates of heart failure when used concomitantly with insulin.

**PREGNANCY AND LACTATION:** ***Pregnancy***: Insulin requirements may vary during pregnancy and should be assessed frequently. ***Lactation***: Caution. Lactating women may require adjustments in insulin dose and diet.

**SIDE EFFECTS:** Hypoglycaemia, hypokalaemia, weight gain, lipodystrophy and cutaneous amyloidosis at injection site, generalized hypersensitivity (urticaria, rash, dyspnea, wheezing), neuropathic pain, allergic reactions to phenol, m-cresol, zinc, protamine or excipients, local allergic reactions to insulin (e.g. pruritus, erythema and oedema), stinging/burning at injection site Rare: anaphylaxis, severe 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:** July 2025

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