

Hypurin®

INSULIN Ph Eur

Important Hypurin® Bovine Insulin Discontinuation Information

August 2019 UPDATE



ALL PATIENTS USING HYPURIN® BOVINE INSULIN WILL NEED TO HAVE THEIR PRESCRIPTION CHANGED

- Due to global bovine insulin API (raw material) unavailability, Wockhardt have no choice but to discontinue the Hypurin® Bovine Insulin range. Unfortunately, despite our best efforts in trying to source an alternative supply, none has been found
- As bovine insulin API is no longer available to manufacture further batches, residual bovine insulin stocks will be carefully managed to ensure product remains available for patients for as long as possible
- **PLEASE NOTE:** the discontinuation of Hypurin® BOVINE Insulin **does not** affect the supply of Hypurin® PORCINE Insulin
- Wockhardt apologises for any inconvenience this may cause but unfortunately the withdrawal is due to circumstances beyond our control. Further information and support materials can be accessed via our website: www.wockhardt.co.uk
- For general enquiries call +44 1978 661261 or email: hypurin-insulin@wockhardt.co.uk
For medical information call +44 1978 669260 or for supply enquiries call +44 1978 669359

Insulin range and activity profiles

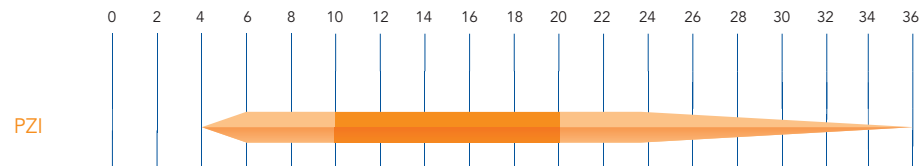
...onset, peak activity and duration in approximate hours



Hypurin® Bovine is being withdrawn

Our **BOVINE INSULIN RANGE** is being discontinued. All patients using any of these bovine insulins will need to have their prescription changed

Hypurin® Bovine



The table below indicates the likely stock depletion date for each Hypurin® Bovine Insulin

Hypurin® Bovine	10ml Vial	3ml Cartridge*
Isophane	Depleted (Jul 18)	Depleted (Dec 17)
Neutral	Depleted (Aug 19)	Depleted (May 19)
Lente	Depleted (May 19)	N/A
PZI	September 2019	N/A

Monthly updates regarding predicted depletion dates will be posted on the Wockhardt UK website (www.wockhardt.co.uk)

Please note: Hypurin® Bovine Isophane Neutral and Lente Insulins are NO LONGER AVAILABLE in any form

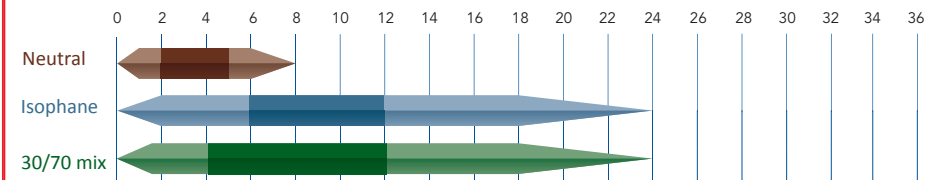
Bovine Insulin to be withdrawn	Alternative Porcine continued availability
Hypurin® Bovine Neutral	Hypurin® Porcine Neutral

The discontinuation of Hypurin® BOVINE Insulin does not affect the supply of Hypurin® PORCINE Insulin. Wockhardt manufacture a Porcine Neutral which has a similar profile of action to our Bovine Neutral.

Hypurin® Porcine remains available

Our **PORCINE INSULIN RANGE** is **NOT** affected by the Bovine API issue and **REMAINS AVAILABLE**

Hypurin® Porcine



Porcine insulins are available in the following presentations:

Hypurin® Porcine	10ml Vial	3ml Cartridge*
Neutral	✓	✓
Isophane	✓	✓
30/70 mix	✓	✓

*Hypurin Insulin 3ml cartridges fit in the **Autopen® Classic** pen-injector device, available on prescription and made by Owen Mumford
www.owenmumford.com

Hypurin®
INSULIN Ph Eur



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 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. 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 Protamine Zinc: 10ml vials: £27.72

MARKETING AUTHORISATION NUMBERS: 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: Aug 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).