

May 2019

Important – Hypurin[®] Bovine Insulin Discontinuation Patient Information

In July 2017 it was announced that Hypurin[®] Bovine insulin is being discontinued. All Patients currently using any Hypurin[®] Bovine insulin will need to have their insulin prescription changed. Wockhardt regrets any inconvenience this may cause but unfortunately the circumstances are beyond our control.

Questions and Answers

Q: Why is Hypurin[®] Bovine Insulin being withdrawn?

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.

Q: Will this affect the supply of Hypurin[®] Porcine insulin?

No. The discontinuation of Hypurin[®] BOVINE insulin **does not** affect the supply of PORCINE insulin. Please ensure the discontinuation information is ONLY given to Hypurin[®] Bovine Insulin patients in order to avoid unnecessary confusion and upset

Q: When are stocks of Bovine Insulin likely to run out?

As we are unable to manufacture further batches, residual bovine insulin stocks will be carefully managed to ensure product remains available for patients for as long as possible

The table below indicates the likely stock depletion date for each Hypurin[®] Bovine Insulin (based on current demand and stock inventories). Wockhardt will be updating this monthly with any changes.

| Description | Form | Predicted depletion date |
|--|---------------------------|-------------------------------------|
| Hypurin[®] Bovine Isophane | 3ml Cartridges | Depleted (December 2017) |
| Hypurin[®] Bovine Isophane | 10ml Vial | Depleted (July 2018) |
| Hypurin[®] Bovine Neutral | 3ml Cartridges | Depleted May 2019 |
| Hypurin[®] Bovine Lente (I.ZS) | 10ml Vial | Depleted May 2019 |
| Hypurin [®] Bovine Neutral | 10ml Vial | June 2019 |
| Hypurin [®] Bovine PZI | 10ml Vial | October 2019 |

Due to the product expiry dates of Bovine Neutral Vials and Bovine PZI Vials, the final acceptance of orders/prescriptions by wholesaler and pharmacies may be 2-3 months prior to the depletion date

Where can I get more information and advice?

Q:

For general enquires call **+44 1978 661261** or email hypurin-insulin@wockhardt.co.uk
 For medical Information call **+44 1978 669260** or email drug.safety@wockhardt.co.uk
 For supply enquires call **+44 1978 669 359** or email customer.services@wockhardt.co.uk
 For overseas non UK enquires call **+44 1978 669201** or email export@wockhardt.co.uk

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 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).