Huminsulin® 30/70

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PHARMACEUTICAL FORM

Huminsulin® 30/70 is a sterile suspension of human insulin in the proportion of 30% soluble insulin to 70% isophane insulin.

One cartridge contains 3 mL equivalent to 300 IU of biphasic isophane insulin (Biphasic isophane insulin injection – 30% soluble insulin / 70% isophane insulin).

NAME OF THE MEDICINAL PRODUCT

Huminsulin® 30/70 100 IU/mL suspension for injection in cartridge (Biphasic isophane insulin injection – 30% soluble insulin / 70% isophane insulin)

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL contains: 100 IU Human Insulin (N·E·O·insulin, or active insulin, 1.6 mg crystals/P, Na, ascorbic acid, 0.6 mg Glycine P as an isocitric acid, 0.6 mg Phosphoric Acid as, Protamine Sulphate P (for complexing with insulin to prolong action), 0.25 mg Sodium Phosphate P., Na, as buffer, Zinc Oxide, P.S. as stabilizer, Hydrochloric Acid Solution 10% + 0.1 mL Sodium Hydroxide Solution 10% to pH adjustment. Water for Injection P. 4.9 mL. 1 mL corresponds to 100 IU human insulin (produced in E. coli) by recombinant DNA technology.

One cartridge contains 3 mL equivalent to 300 IU of biphasic isophane insulin.

For exceptions, see section List of excipients.

CONTRAINDICATIONS

Huminsulin® 30/70 is contraindicated in:

- Patients with known hypersensitivity to human insulin or any other component of the product.
- Patients with conditions that may affect glucose metabolism.

The physician should take possible interactions into account and ask patients if they are pregnant or are contemplating pregnancy.

- Patients taking beta-blockers, angiotensin converting enzyme (ACE) inhibitors (captopril, enalapril), angiotensin II receptor blockers, non-selective beta-blockers (such as lidocaine, halothane, terbutaline), thiazides.

- Patients with a history of severe allergic reactions (anaphylaxis) to human insulin.

PHYSICAL AND METHOD OF ADMINISTRATION

The dosage should be determined by the physician, according to the requirement of the patient.

- Huminsulin® 30/70 should be given by subcutaneous injection but may, although not recommended, also be given by intramuscular injection.

Infections may change significantly in diseases of the adrenal, hypothalamus, and/or method of manufacture (recombinant DNA versus animal-insulin).

- Huminsulin® 30/70 should not be administered intravenously.

- Subcutaneous administration should be in the upper arms, thighs, buttocks or abdomen. Use of injection sites should be rotated so that the same site is not used more than approximately once a month.

Some medicinal products are known to interact with glucose metabolism.

- The physician should take possible interactions into account and ask patients if they are pregnant or are contemplating pregnancy.

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- Patients with a history of severe allergic reactions (anaphylaxis) to human insulin.

It is essential to maintain good control of the insulin treated (insulin-dependent or gestational) patient throughout pregnancy.

In patients with diabetes who are lactating, the insulin requirements usually fall during the first trimester and increase during the second and third trimesters.

- Patients with diabetes who are lactating may require adjustments in insulin dose and/or diet.

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- Effects on ability to drive and use machines

Patients should be advised to use precautions to avoid hypoglycaemia while driving, especially in those who have reduced or absent awareness of the warning signs of hypoglycaemia or have frequent episodes of hypoglycaemia.

The advisability of driving should be considered in these circumstances.

- Undesirable effects

Hypoglycaemia is the most frequent undesirable effect of insulin therapy. A patient with diabetes may suffer. Severe hypoglycaemia may lead to
loss of consciousness, and in extreme cases, death. No specific frequency for hypoglycaemia is presented, since hypoglycaemia is a result of both the insulin dose and other factors such as size of dose, site of injection temperature and physical activity factors such as size of dose, site of injection temperature and physical activity. Within muscle tissue this includes increasing glycogen, fatty acid, glycerol and protein synthesis and amino acid availability and other metabolic processes. Hypoglycaemia may occur as a result of an excess of insulin relative to food intake and energy expenditure. Hypoglycaemia may be associated with headache, sweating and vomiting. Mild hypoglycemic episodes will respond to oral administration of glucose or sugar products. Severe hypoglycaemic episodes will respond to insulin injection or intravenous glucose. In severe cases of hypoglycaemia, intravenous dextrose may be necessary. Carbohydrates must be given intravenously, if the patient is comatose, glucagon should be administered intramuscularly. Severe hypoglycaemia may be associated with headaches, sweating and vomiting. The prime activity of insulin is the regulation of glucose metabolism. Insulin has no specific overdose definitions, because serum glucose concentrations as a result of complex interactions between insulin levels, glycaemic availability and other metabolic processes. Hypoglycaemia may occur as a result of an excess of insulin relative to food intake and energy expenditure.

Hormone. Therefore, it is more appropriate to examine glucose utilisation curves (as discussed above) when considering the activity of insulin. Pharmacokinetic properties of insulin do not reflect the metabolic action of that hormone. Therefore, it is more appropriate to examine glucose utilisation curves (as discussed above) when considering the activity of insulin.

Huminsulin® is human insulin produced by recombinant technology. No other manufacturers or with animal insulin preparations. No severe events have been reported in subchronic toxicology studies. The typical activity profile (glucose utilisation curve) following subcutaneous injection is illustrated below by the heavy line. Variations in the insulin dose and other factors e.g. a patient`s level of diet and exercise. The following may be used to adjust pH, hydrochloric acid and/or sodium bicarbonate. The typical activity profile (glucose utilisation curve) following subcutaneous injection is illustrated below by the heavy line. Variations in the insulin dose and other factors e.g. a patient`s level of diet and exercise. The following may be used to adjust pH, hydrochloric acid and/or sodium bicarbonate.