Insul™ R

Insulin Human USP (rDNA)

Presentation

Insul™ R 100 IU/ml Injection: Each ml solution contains 100 IU Insulin Human USP (recombinant DNA origin).

Insul™ R 40 IU/ml Injection: Each ml solution contains 40 IU Insulin Human USP (recombinant DNA origin).

Description

Insul™ R is a sterile, clear, colorless solution of Insulin Human. It is a fast-acting insulin and has a relatively short duration of action as compared with other insulins. It may be used in combination with long-acting insulins.

Mechanism of Action

The blood glucose lowering effect of insulin is due to the facilitated uptake of glucose following binding of insulin to receptors on muscle and fat cells and to the simultaneous inhibition of glucose output from the liver.

Pharmacokinetics

Insulin has a half-life of a few minutes in the blood stream.
No profound binding to plasma proteins.
An average action profile after subcutaneous injection indicates: Onset of action- within 30 minutes; Peak plasma levels attained between 1-3 hours; Duration of action- approximately 4-6 hours

Indications

- Treatment of all patients with type 1 diabetes
- Treatment of patients with type 2 diabetes who are not adequately controlled by diet and/ or oral hypoglycemic agents
- For the initial stabilization of diabetes in patients with diabetic ketoacidosis, hyperosmolar non-ketotic syndrome and during periods of stress such as severe infections and major surgery in diabetic patients
- Treatment of gestational diabetes

Dosage

Dosage is individual and determined by the physician in accordance with the needs of the patient.
The average range of total daily insulin requirement for maintenance therapy in type 1 diabetic patients lies between 0.5 and 1.0 IU/Kg. In pre-pubertal children it usually varies from 0.7 to 1.0 IU/ Kg.
The daily insulin requirement may be higher in patients with insulin resistance (e.g. during puberty in the young or due to obesity) and lower in patients with endogenous insulin production or during the period of partial remission.
Initial dosage for type 2 diabetic patients are often lower, e.g. 0.3 to 0.6 IU/ Kg/ Day.
An injection should be followed within 30 minutes by a meal or snack containing carbohydrates.

Administration

It is usually administered subcutaneously in the abdominal wall. The thigh, the gluteal region or the deltoid region may also be used.
Subcutaneous injection into the abdominal wall ensures a faster absorption than from other injection sites.
In order to avoid lipodystrophy, injection sites for a given insulin preparation should be rotated within an anatomic region.
Intramuscular administrations are possible under guidance by a physician. Intravenous administrations should only be carried out by a physician.

Dosage Adjustment

Concomitant illness, especially infections and feverish conditions, usually increases the patient's insulin requirement.
Renal or hepatic impairment may reduce insulin requirement.
Adjustment of the dosage may also be necessary if patients change physical activity or their usual diet.
Dosage adjustment may be necessary when transferring patients from one insulin preparation to another.

Contraindications

Insulin should never be given to patients with hypoglycaemia & hypersensitivity to human insulin or any of the excipients.

Warnings and Precautions

Inadequate dosing or discontinuation of treatment, especially in type 1 diabetes, may lead to hyperglycaemia. In type 1 diabetes, untreated hyperglycaemic events eventually leads to diabetic ketoacidosis which is potentially lethal.
Hypoglycaemia may occur if the insulin dose is too high in relation to the insulin requirement.
Transferring a patient to another type or brand of insulin should be done under strict medical supervision.
Changes in strength, brand (manufacturer), type (rapid acting insulin, dual acting insulin, intermediate and long acting insulin etc.), species (animal, human insulin analogue) and/or method of manufacture (recombinant DNA versus animal source insulin) may result in the need for a change in dosage.
Before travelling between different time zones, the patients should be advised to consult the doctor, since this may mean that the patients have to take insulin and meals at different time.

Pregnancy and Lactation

There are no restrictions on the treatment of diabetes with insulin during pregnancy as insulin does not pass the placental barrier.
Both hypoglycaemia and hyperglycaemia, which can occur in inadequately controlled diabetes therapy, increase the risk of malformations and death in utero.
Insulin requirements usually fall in the first trimester and increase subsequently during the second and third trimesters. After delivery, insulin requirements return rapidly to pre-pregnancy values.
Insulin treatment of the nursing mother involves no risk to the baby. However, the insulin dosage, diet or both may need to be adjusted.

Adverse Effects

Adverse drug reactions observed in patients using human insulin are mainly dose-dependent and due to the pharmacologic effect of insulin. As for other insulin products, hypoglycaemia, in general is the most frequently undesirable effect. It may occur if the insulin dose is too high in relation to the insulin requirement.
Lipodystrophy may occur at the injection site as a consequence of failure to rotate injection sites within an area.
Symptoms of generalized hypersensitivity may include generalized skin rash, itching, sweating, gastrointestinal upset and angioneurotic oedema, difficulties in breathing, palpitation and reduction in blood pressure. Generalised hypersensitivity reactions are potentially life threatening.
Oedema may occur upon initiation of insulin therapy. These symptoms are usually of transitory nature.

Interaction

Concomitant use of other drugs may influence insulin requirements.
The following substances may reduce the insulin requirements: Oral hypoglycaemic agents (OHA), monoamine oxidase inhibitors (MAOI), non-selective beta-blocking agents, angiotensin converting enzyme (ACE) inhibitors, salicylates and alcohol.

The following substances may increase the insulin requirements: Thiazides, glucocorticoids, thyroid hormones and beta-sympathomimetics, growth hormone and danazol.

Beta-blockers may mask the symptoms of hypoglycaemia and delay recovery from hypoglycaemia. Octreotide/lanreotide may both increase and decrease insulin requirement. Alcohol may intensify and prolong the hypoglycaemic effect of insulin.

Overdosage

Insulins have no specific overdose definitions. However, hypoglycaemia may develop over sequential stages:
- Mild hypoglycaemic episodes can be treated by oral administration of glucose or sugery products.
- Severe hypoglycaemic episodes, where the patient has become unconscious, can be treated by glucagon (0.5 to 1 mg) given intramuscularly or subcutaneously by a trained person or glucose given intravenously by a medical professional. Glucose must also be given intravenously, if the patient does not respond to glucagon within 10 to 15 minutes.

Upon regaining consciousness administration of oral carbohydrate is recommended for the patient in order to prevent relapse.

Pharmaceutical Precautions

Insulin preparations should be stored between 2°C and 8°C (in a refrigerator). Insulin preparations which have been frozen must not be used.
Insulin preparation should be kept in the outer carton in order to protect from light.
Insulin preparations should be protected from excessive heat or sunlight. Insulin solutions should not be used if they do not appear water-clear and colorless.
When in use the vial should not be refrigerated. Once in use the vial may be used for up to 6 weeks when stored below 25°C or 4 weeks when stored below 30°C.

Commercial Pack

Insul™ R 100 IU/ml Injection : Each box contains 10 ml vial.
Insul™ R 40 IU/ml Injection : Each box contains 10 ml vial.

Manufactured by :

POPULAR

POPULAR PHARMACEUTICALS LTD.
TONGI, GAZIPUR, BANGLADESH