

Rapilog™

Insulin Aspart USP

Presentation

Rapilog™ Injection: Each ml solution contains 100 IU (equivalent to 3.50 mg) Insulin Aspart USP.

Rapilog™ Pen cartridge: Each ml solution contains 100 IU (equivalent to 3.50 mg) Insulin Aspart USP.

Description

Rapilog™ (insulin aspart injection) is a rapid-acting human insulin analog used to lower blood glucose. Rapilog™ is homologous with regular human insulin with the exception of a single substitution of the amino acid proline by aspartic acid in position B28, and is produced by recombinant DNA technology.

Indications

Rapilog™ is an insulin analog indicated to improve glycemic control in patients with diabetes mellitus.

Usage

1. *Prepare before use:*

Cartridge: According to the instruction of AnsuPen® and AnsuPen® Twist, insert the Rapilog™ Cartridge into the pen correctly and equip the needle.

Adjust the dosage button to get correct dose. After removal of the needle cap and discharge the air bubbles in the cartridge, it is ready to be injected in order to avoid cross contamination, do not let the needle touch anything during the process of preparation.

Vial:

- Firstly, clean your hands. Shake or rotate the vial gently to mix the solution uniformly and check if the insulin has the normal appearance.

- If using a new Rapilog™ bottle, then flip off the plastic protective cap and wipe the rubber stopper with an alcohol swab.

- Draw air into your syringe equal to the amount of Rapilog™ needed. Puncture the needle into the vial and inject the air.

- Turn the bottle and syringe upside down. Withdraw correct dose of Rapilog™ into the syringe. Before pulling out the needle, check if there are any bubbles remain in the syringe. If so, put the syringe upright and tap the syringe to discharge the air bubbles.

2. *Injection Site:*

Choose the area such as upper arm, thigh, buttock and abdomen, etc. To avoid tissue damage, choose a site for each injection that is at least 1 cm from the previous injection site.

3. *Injection Method:*

Cleanse the skin with alcohol where the injection is to be made. Put the needle in such a position as to form 45° angle with the skin. Pinch the skin with finger & puncture the needle into skin and inject insulin. Then pull the needle out and apply gentle pressure over the injected site for several seconds. Do not rub the injection site.

Dosage & Administration

Rapilog™ has a faster onset and a shorter duration of action than soluble human insulin. Due to the faster onset of action, Rapilog™ should generally be given immediately before a meal. When necessary Rapilog™ may be given soon after a meal.

Dosage of Rapilog™ is individual and determined on the basis of the physician's advice in accordance with the needs of the patient. It should normally be used in combination with long-acting insulin given at least once a day.

The individual insulin requirement is usually between 0.5 and 1.0 IU/kg/day in adults and children over 2 years of age. In a meal-related treatment 50-70% of this requirement may be provided by Rapilog™ and the remainder by long-acting insulin. Adjustment of dosage may also be necessary if patients undertake increased physical activity or change their usual diet. Exercise taken immediately after a meal may increase the risk of hypoglycaemia.

Subcutaneous Injection

Rapilog™ should be administered by subcutaneous injection in the abdominal region, buttocks,

thigh, or upper arm. Because Rapilog™ has a more rapid onset and a shorter duration of activity than human regular insulin, it should be injected immediately (within 5-10 minutes) before a meal

Intravenous Use

Rapilog™ can be administered intravenously under medical supervision for glycemic control with close monitoring of blood glucose and potassium levels to avoid hypoglycemia and hypokalemia. For intravenous use, Rapilog™ should be used at concentrations from 0.05 IU/mL to 1.0 IU/mL insulin aspart in infusion systems using polypropylene infusion bags. Rapilog™ has been shown to be stable in infusion fluids such as 0.9% sodium chloride.

Use in Pregnancy & Lactation

Pregnancy: Pregnancy category B.

Lactation: There are no restrictions on treatment with Rapilog™ during lactation. Insulin treatment of the nursing mother should not affect the baby. However, dosage may need to be adjusted.

Side Effects

Side effects of Insulin Aspart are hypoglycemia, allergic reactions, injection site reaction, lipodystrophy, pruritus and rash.

Precautions

Dose adjustment and monitoring: Blood glucose should be monitored in all patients treated with insulin. Insulin regimens should be modified cautiously and only under medical supervision.

Contraindications

- Hypoglycemia
- In patients with hypersensitivity to Insulin Aspart or any of its excipients.

Drug Interaction

A number of drugs affect glucose metabolism and may require dose adjustment.

The following substances may reduce the Insulin as well as Insulin Aspart requirements:

Antidiabetic agents, angiotensin converting enzyme inhibitors, angiotensin II receptor blocking agents, disopyramide, fibrates, fluoxetine, monoamine oxidase inhibitors, pentoxifylline, pramlintide, propoxyphene, salicylates, somatostatin analogs and sulfonamide antibiotics.

The following substances may increase the Insulin as well as Insulin Aspart requirements:

atypical antipsychotics (e.g., olanzapine and clozapine), corticosteroids, danazol, diuretics, estrogens, glucagon, isoniazid, niacin, oral contraceptives, phenothiazines, progestogens, protease inhibitors, somatropin, sympathomimetic agents (e.g., albuterol, epinephrine, terbutaline) and thyroid hormones.

Overdose

A specific overdose for insulin cannot be defined, however, hypoglycaemia may develop over sequential stages.

Mild hypoglycaemic episodes can be treated by oral administration of glucose or sugary products.

Severe hypoglycaemic episodes, where the patient has become unconscious, can be treated by glucagon (0.5 to 1 mg) given intramuscularly or subcutaneously. 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.

Storage

Store at 2° C to 8° C in a refrigerator. Do not freeze. Keep out of reach of the children. Protect from light.

How supplied

Rapilog™ Injection: Each box contains 1 vial of 3 ml Insulin Aspart USP.

Rapilog™ Pen Cartridge: Each box contains 1 pen cartridge of 3 ml Insulin Aspart USP.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH