RapiMix™ 30/70

30% Soluble Insulin Aspart &
70% Insulin Aspart Protamine

Composition
Rapimix™ 30/70 injection: Each mL suspension contains Insulin Aspart USP 100 IU (equivalent to 3.5 mg) as 30% Soluble Insulin Aspart and 70% Insulin Aspart Protamine
Rapimix™ 30/70 Pen cartridge: Each mL suspension contains Insulin Aspart USP 100 IU (equivalent to 3.5 mg) as 30% Soluble Insulin Aspart and 70% Insulin Aspart Protamine

Pharmacology
Rapimix™ (30% Soluble insulin aspart and 70% insulin aspart protamine suspension injection) is a human insulin analog suspension containing 70% insulin aspart protamine crystals and 30% soluble insulin aspart. Rapimix™ is a blood glucose lowering agent with an earlier onset and an intermediate duration of action. Rapimix™ 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
Rapimix™ is an insulin analog indicated to improve glycemic control in adults and children with diabetes mellitus.

Usage
1. Prepare before use:
Cartridge: According to the instruction of AnsuPen® and AnsuPen® Twist, insert the Rapimix™ Cartridge into the pen correctly and equip the needle. Gently turn the pen upside down for 8-10 times until the insulin in the cartridge becomes uniformly mixed.
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 Rapimix™ 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 Rapimix™ needed. Puncture the needle into the vial and inject the air.
• Turn the bottle and syringe upside down. Withdraw correct dose of Rapimix™ 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 where skin is less tight, 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. 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
Rapimix™ is an insulin analog with an earlier onset and intermediate duration of action in comparison to the basal human insulin premix. The addition of protamine to the rapid-acting insulin aspart results in insulin activity that is 30% short-acting and 70% long-acting. Rapimix™ is typically dosed on a twice-daily basis. The dosage of Rapimix™ must be individualized.
Rapimix™ should appear uniformly white and cloudy. Do not use it if it looks clear or if it contains solid particles.
Rapimix™ should be administered by subcutaneous injection in the abdominal region, buttocks, thigh, or upper arm. Rapimix™ has a faster onset of action than human insulin premix 70/30 and should be dosed within 15 minutes before meal initiation for patients with type 1 diabetes. For patients with type 2 diabetes, dosing should occur within 15 minutes before or after meal initiation.
Rapimix™ should not be administered intravenously or used in insulin infusion pumps. Dose regimens of Rapimix™ will vary among patients and should be determined by the doctors with the patient's recommended glucose treatment goals, metabolic needs, eating habits, and other lifestyle variables.

Use in Pregnancy & Lactation
Pregnancy: Pregnancy category B.
Lactation: It is unknown whether insulin aspart is excreted in human milk as occurs with human insulin. There are no adequate and well-controlled studies of the use of Insulin Aspart 70/30 or Insulin Aspart in lactating women. Women with diabetes who are lactating may require adjustments of their insulin doses.

Side Effects
Hypoglycemia, allergic reactions, injection site reaction, lipodystrophy, pruritus, weight gain, peripheral edema 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.

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

Drug Interaction
The following may increase the blood glucose lowering effect and susceptibility to hypoglycemia: antidiabetic products, pramlintide, ACE inhibitors, disopyramide, fibrates, fluoxetine, monoamine oxidase (MAO) inhibitors, propoxyphene, salicylates, somatostatin analog, sulfonamide antibiotics
The following may reduce the blood-glucose-lowering effect: corticosteroids, niacin, danazol, diuretics, sympathomimetic agents (e.g., epinephrine, salbutamol, terbutaline), isoniazid, phenothiazine derivatives, somatropin, thyroid hormones, estrogens, progestogens (e.g., in oral contraceptives), atypical antipsychotics

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. Protect from light.

How supplied
Rapimix™ 30/70 Injection: Each box contains 1 vial of 3 ml Rapimix™.
Rapimix™ 30/70 Pen Cartridge: Each box contains 1 cartridge of 3 ml Rapimix™ .

Manufactured by
SQUARE PHARMACEUTICALS PLC.
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