

Composition : Mysulin 30/70 injection 40 IU: Each ml suspension contains Insulin Human (rDNA) USP 40 IU (equivalent to 1.388 mg) as 30% soluble Insulin (Regular) and 70% Isophane Insulin.

Mysulin 30/70 injection 100 IU: Each ml suspension contains Insulin Human (rDNA) USP 100 IU (equivalent to 3.47 mg) as 30% soluble Insulin (Regular) and 70% Isophane Insulin.

Mysulin 30/70 injection 100 IU Penset: Each ml suspension contains Insulin Human (rDNA) USP 100 IU (equivalent to 3.47 mg) as 30% soluble Insulin (Regular) and 70% Isophane Insulin.

Mysulin 50/50 injection 100 IU: Each ml suspension contains Insulin Human (rDNA) USP 100 IU (equivalent to 3.47 mg) as 50% Soluble Insulin Human (Regular) and 50% Isophane Insulin.

Mysulin 50/50 injection 100 IU Penset: Each ml suspension contains Insulin Human (rDNA) USP 100 IU (equivalent to 3.47 mg) as 50% Soluble Insulin Human (Regular) and 50% Isophane Insulin Human.

Mysulin-R 40 IU injection: Each ml solution contains Insulin Human (rDNA) USP 40 IU (equivalent to 1.388 mg) as Soluble Insulin Human (Regular).

Mysulin-R 100 IU injection: Each ml solution contains Insulin Human (rDNA) USP 100 IU (equivalent to 3.47 mg) as Soluble Insulin Human (Regular).

Pharmacology: Mysulin is human insulin made by DNA recombinant technology so it has the same structure and function as natural insulin. The product can regulate the glucose metabolism and stimulate the ingestion and utilization of glucose by liver, muscles, and fat tissue. It can accelerate the transformation from glucose to glycogen stored in muscles and liver and inhibit the gluconeogenesis, thus, to lower the blood glucose.

Indications : It is indicated as an adjunct to diet and exercise to improve glycaemic control in adult patients with type 1 and type 2 diabetes mellitus.

Instructions to be given to the patient

Vial :

Before injecting this insulin :

1. Disinfect the rubber stopper.
2. If suspension, roll the vial between the palms of the hands until the liquid is uniformly white and cloudy.
3. Draw into the syringe the same amount of air as the dose of insulin to be injected.
4. Inject the air into the vial.
5. Turn the vial and syringe upside down and draw the correct insulin dose into the syringe. Withdraw the needle from vial and expel the air from the syringe and check that the dose is correct.
6. Inject immediately.

Cartridge

Before injecting this insulin:

1. According to the instruction given with MyPen, insert the Mysulin cartridge into the pen correctly & equip the needle.
2. In case of Mysulin 30/70, Mysulin 50/50, gently turn the pen upside down for 8-10 times until the insulin in the cartridge becomes uniformly mixed suspension.
3. Remove the needle cap, discharge air bubbles in the cartridge.
4. Adjust the dosage button to get correct dose & inject to the specific site.
5. In order to avoid cross contamination, do not let the needle touch anything during the process of preparation.

For detail description, please see the Patient Instruction Leaflet provided with MyPen.

Injection Site : Choose the area where skin is less tight, such as the 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.

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 : The dosage and administration time of the insulin are different due to the individual differences of each patient. It should be given subcutaneously approximately 15-30 minutes before a meal. The

Mysulin Sterile Injection



average range of total daily insulin requirement for maintenance therapy in type 1 diabetic patients lies between 0.5 and 1.0 IU/kg/day. However, in prepubertal children it usually varies from 0.7 to 1 IU/kg/day. In situations of insulin resistance, e.g. during puberty or due to obesity, the daily insulin requirement may be substantially higher. Initial dosages for patients with diabetes are often lower, e.g., 0.3 to 0.6 IU/kg/day.

- An injection should be followed by a meal or snack containing carbohydrates within 30 minutes.

- The preparations are administered subcutaneously in the thigh or abdominal wall. A subcutaneous injection into the abdominal wall results in a faster absorption than from other injection sites.

- Insulin suspensions are never to be administered intravenously. Or, as directed by the registered physician.

Side effects : The most common side effect is hypoglycemia. Few cases of allergic reaction such as red and swollen or itching are reported. It usually disappears in a few days. In some instances, the allergy may be caused by other reasons rather than insulin, such as disinfectant and poor injection technique.

Contraindication : It is contraindicated during episodes of hypoglycemia and in patients who have had hypersensitivity reactions to insulin or any of its excipients.

Use in pregnancy and lactation : There are no restrictions on the treatment of diabetes with insulin during pregnancy, as insulin does not pass the placental barrier. Insulin treatment of the nursing mother presents no risk to the baby.

Precautions : Insufficient dosing or discontinuation of insulin may cause hyperglycemia. Change of meal time or excessive physical exercise, high dose in relation to the insulin requirement may lead to hypoglycemia.

Drug interactions : When using drugs with hypoglycemic activities, salicylates, sulfonamide antibiotics, monoamine oxidase inhibitors, antidepressants & ACE inhibitors, which will result in the decrease of blood glucose, the dosage of insulin should be reduced. Oral contraceptive drugs, adrenal cortical hormone, thyroid hormone etc may increase the blood glucose level, so, the amount of insulin should be increased.

Overdose : Insulin have no specific overdose definitions. However, hypoglycaemia may develop over sequential stages:

- Mild hypoglycaemic episodes can be treated by oral administration of glucose or sugary products. It is therefore recommended that the diabetic patient constantly carries some sugar lumps, sweets, biscuits or sugary fruit juice.

- 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 - 8°C in a refrigerator. Do not freeze. In case of insulin for recent use need not be refrigerated, try to keep it in a cool place and keep away from heat and light. The insulin in use can be kept under the room temperature for a month.

Packing : Mysulin 30/70 injection 40IU: Each box contains 10ml glass vial.

Mysulin 30/70 injection 100IU: Each box contains 10ml glass vial.

Mysulin 30/70 injection 100IU Penset: Each box contains 3x3ml glass cartridges.

Mysulin 50/50 injection 100IU: Each box contains 10ml glass vial.

Mysulin 50/50 injection 100IU Penset: Each box contains 3x3ml glass cartridges.

Mysulin-R 40IU: Each box contains 10ml glass vial.

Mysulin-R 100IU: Each box contains 10ml glass vial.