Only for the use of Medical Professionals

Diasulin®

Insulin Human (rDNA) USP Sterile injection

Description

Diasulin® 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.

Pharmacokinetic profiles of different Diasulin® preparations are as follows:

	Onset of action	**Time to reach Cmax (Tmax)**	**Duration of action**
Diasulin® R	30 min	1 – 3 hours	4 – 6 hours
Diasulin® N	1-2 hours	6 – 12 hours	18 – 24 hours
Diasulin® 30/70	30 min	2 – 12 hours	18 – 24 hours
Diasulin® 50/50	30 min	2 –12 hours	18 – 24 hours

Indications

Diasulin® is indicated for the following conditions:

- Patients with type-1 Diabetes Mellitus.
- Patients with type-2 Diabetes Mellitus who are not adequately controlled by diet and/oral hypoglycemic agents.
- Diabetes Mellitus in patients with diabetic ketoacidosis, hyperosmolar non-ketotic syndrome and during periods of stress such as severe infections and major surgery in diabetic patients.
- In gestational diabetes

Usage

1. **Diasulin®** should be injected subcutaneously 15 minutes to one hour before meal. The exact time for administration is suggested by doctors with regard to each individual's case.

2. Procedure for Insulin Administration

Before going for administration of **Diasulin®** please follow the below mentioned check list:

- Insulin syringe of the right size
- Prescribed type of **Diasulin®** injection
- Check the expiry date on **Diasulin®** vial
- Ensure that the flip-off cap on the **Diasulin®** vial is intact

After that follow the below mentioned instructions as per given picture:

1. Wash the hands carefully. Shake or roll **Diasulin®** vial 10 times to completely mix the insulin.

2. Inspect the vial. **Diasulin®**R should appear as clear colorless solution. **Diasulin®** N , **Diasulin®** 30/70, **Diasulin®** 50/50 should be uniformly millky or cloudy.

3. When using a new vial, flip off the plastic protective cap, but do not remove the stopper. The tip of the vial should be wiped an alcohol swab.

4. Draw air in to the syringe equal to your insulin dose.

5. Insert needle in to vial through rubber top & push plunger to empty the air in to the vial.

6. Turn the bottle and syringe upside down. Hold the bottle and syringe firmly in one hand and shake gently. Make sure that the tip of the needle is in the liquid; withdraw the correct dose of insulin into the syringe.

7. Before removing the needle from the vial, check the insulin syringe for air bubbles, which reduces the amount of insulin in it, if bubbles are present, hold the insulin straight up and tap its side until the bubbles float to the top. Push them out with the plunger and withdraw the correct dose again.

8. Lightly pinch up the skin, holding the syringe like a pencil.

9. Insert the needle in to the skin & push the plunger slowly. Make sure that the needle is all the way in.

10. Wait for 5 seconds & pull out the syringe. Do not rub the area.

Dosage

The dosage form, the dosage and the administration time of the insulin are different due to the individual differences of each patient. In addition, the dosage is also affected by food, working style and exercising intensity. Therefore, patients should use the insulin under doctor's instruction.

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 1.0IU/kg, whereas in insulin resistant cases, e.g. during puberty or due to obesity, the daily insulin requirement may be substantially higher. Initial dosages for type 2 diabetic patients are often lower, e.g., 0.3 to 0.6 IU/kg/day.

Pregnancy & lactation

There are no restrictions on 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.

Side Effects

Hypoglycemia is the most common side effect during insulin treatment and symptoms of hypoglycemia may occur suddenly. Few cases of the 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.

Contraindications

Hypoglycemia or the patients who have allergic reaction to insulin or any of the excipients.

Precautions

Inadequate dosing or discontinuation especially in type 1 diabetes, may lead to hyperglycemia. Hypoglycemia may occur if the insulin dose is too high in relation to the insulin requirement. Omission of a meal or unplanned, strenuous physical exercise may lead to hypoglycemia.

Drug Interactions

When using oral contraceptive drug, adrenal cortical hormone, hypothyroid hormone, etc., the drugs that can result in the rise of blood glucose; you might need to increase the amount of Insulin. When using drugs with hypoglycemic activities, salicylate, sulfanilamide and other anti-depressants, which will result in the decrease of blood glucose, the dosage of insulin should be reduced.

Over dosage

Insulin overdose may result in hypoglycemia. Mild episodes of hypoglycemia can usually be treated with oral carbohydrates. Severe hypoglycemia may be treated with parenteral glucose or injections of glucagon. Adjustments in drug dosage, meal patterns, or exercise may be needed.

Pharmaceutical precautions/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.

Presentation

Diasulin® R Injection 40 IU/ml: Each ml solution contains Insulin Human (rDNA) USP 40 IU (equivalent to 1.388 mg) as Soluble Insulin Human (Regular).

Diasulin® R Injection 100 IU/ml: Each ml solution contains Insulin Human (rDNA) USP 100 IU (equivalent to 3.47 mg) as Soluble Insulin Human (Regular).

Diasulin® N Injection 40 IU/ml: Each ml suspension contains Insulin Human (rDNA) USP 40 IU (equivalent to 1.388 mg) as Isophane Insulin Human.

Diasulin® N Injection 100 IU/ml: Each ml suspension contains Insulin Human (rDNA) USP 100 IU (equivalent to 3.47 mg) as Isophane Insulin Human.

Diasulin® 30/70 Injection 40 IU/ml: Each ml suspension contains Insulin Human (rDNA) USP 40 IU (equivalent to 1.388 mg) as 30% Soluble Insulin Human (Regular) and 70% Isophane Insulin Human.

Diasulin® 30/70 Injection 100 IU/ml: Each ml suspension contains Insulin Human (rDNA) USP 100 IU (equivalent to 3.47 mg) as 30% Soluble Insulin Human (Regular) and 70% Isophane Insulin Human.

Diasulin® 50/50 Injection 40 IU/ml: Each ml suspension contains Insulin Human (rDNA) USP 40 IU (equivalent to 1.388 mg) as 50% Soluble Insulin Human (Regular) and 50% Isophane Insulin Human.

Diasulin® 50/50 Injection 100 IU/ml: 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.

Commercial Pack

Diasulin® R Injection 40 IU/ml: Each box contains 10 ml solution in glass vial.

Diasulin® R Injection 100 IU/ml: Each box contains 10 ml solution in glass vial.

Diasulin® N Injection 40 IU/ml: Each box contains 10 ml suspension in glass vial.

Diasulin® N Injection 100 IU/ml: Each box contains 10 ml suspension in glass vial.

Diasulin® 30/70 Injection 40 IU/ml: Each box contains 10 ml suspension in glass vial.

Diasulin® 30/70 Injection 100 IU/ml: Each box contains 10 ml suspension in glass vial.

Diasulin® 50/50 Injection 40 IU/ml: Each box contains 10 ml suspension in glass vial.

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