

Ansulin™

Insulin Human (rDNA) USP

Pen Cartridge

Sterile injection for subcutaneous use

COMPOSITION

Ansulin™ R Pen Cartridge: Each ml solution contains Insulin Human (rDNA) USP 100 IU (equivalent to 3.47 mg) as Soluble Insulin Human (Regular).

Ansulin™ N Pen Cartridge: Each ml suspension contains Insulin Human (rDNA) USP 100 IU (equivalent to 3.47 mg) as Isophane Insulin Human.

Ansulin™ 30/70 Pen Cartridge: 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.

Ansulin™ 50/50 Pen Cartridge: 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.

PHARMACOLOGY

Ansulin™ 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. Normally, **Ansulin™ R** takes effect within 30 minutes after injection, reaches its peak within 1-3 hours and lasts about 4-8 hours. On the other hand, **Ansulin™ N** comes into effect slowly after injection, reaches its peak within 6-9 hours & lasts about 24 hours. **Ansulin™ 30/70** & **Ansulin™ 50/50** take effect within 30 minutes after injection, reach their peaks within 2-8 hours and last about 24 hours.

INDICATION

Type 1 and Type 2 Diabetes Mellitus.

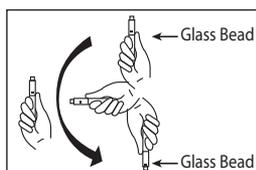
USAGE

1. **Ansulin™** 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. Check whether the specification of the cartridge is the same as doctor's recommendation. Cartridge is designed to be used with **Ansulin™** delivery device. Detailed instructions accompanying the delivery device must be followed.

3. Prepare before use

According to the instruction of **Ansulin™**, insert the **Ansulin™** cartridge into the pen correctly and equip the needle. In case of **Ansulin™ N** or **Ansulin™ 30/70** or **Ansulin™ 50/50**, gently turn the pen upside down (see the picture) for 8-10 times until the insulin in the cartridge becomes uniformly mixed suspension.



Adjust the dosage button to get correct dose. After removal of the needle cap and discharge 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.

4. 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.

5. 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 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 1.0 IU/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.

ADVERSE EFFECT

Hypoglycemia is the most common adverse 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.

CONTRAINDICATION

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

PRECAUTION

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.

PREGNANCY AND 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.

DRUG INTERACTION

When using oral contraceptive drug, adrenal cortical hormone, thyroid 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

Excessive use of insulin may lead to hypoglycemia during the treatment. Slight to moderate hypoglycemia may suddenly occur. It is important to get immediate treatment when hypoglycemia occurs. If you have frequent hypoglycemia, you should consult your doctor to discuss possible changes in therapy, diet plans, and/or exercise programs to help you avoid hypoglycemia.

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.

HOW SUPPLIED

Ansulin™ R Pen Cartridge: Each cartridge contains 3 ml (300 IU) solution.

Ansulin™ N Pen Cartridge: Each cartridge contains 3 ml (300 IU) suspension.

Ansulin™ 30/70 Pen Cartridge: Each cartridge contains 3 ml (300 IU) suspension.

Ansulin™ 50/50 Pen Cartridge: Each cartridge contains 3 ml (300 IU) suspension.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH