

Ansulin[®] D-Pen

Insulin Human USP (rDNA)

Disposable Pen



Composition

Ansulin[®] R D-Pen: Each mL solution contains Insulin Human USP (rDNA) 100 IU (equivalent to 3.47 mg) as Soluble Insulin Human (Regular).

Ansulin[®] 30/70 D-Pen: Each mL suspension contains Insulin Human USP (rDNA) 100 IU (equivalent to 3.47 mg) as 30% Soluble Insulin Human (Regular) and 70% 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.

Ansulin[®] take effect within 30 minutes after injection.

Indications

Type 1 and Type 2 Diabetes Mellitus.

Please read this manual completely and follow the directions carefully before using **Ansulin[®] D-Pen**
Important information

- Always use a new pen needle for each injection.
- Do not store the pen with attached pen needle.
- Always keep the cap on the pen when it is not in use.
- Prior to using the pen always check if the proper pen with the correct drug is chosen as per recommendation of healthcare professionals.
- Always check the expiry date before use.
- To clean the D-pen, a moist cloth is sufficient. Do not use other solvents or cleaning agents.

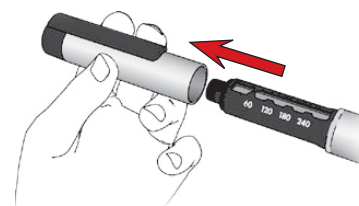
Technical characteristics

Ansulin[®] D-Pen can deliver doses upto 60 units at a time.

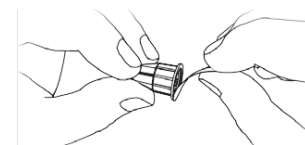
Notes:

- A dose larger than the amount of drug remaining in the pen cannot be dialed.
- If the dose is larger than the remaining drug volume in the cartridge a new pen should be used for the remaining dose.
- Either inject the residual drug and complete the dose with a new pen, or apply the full dose with a new pen.

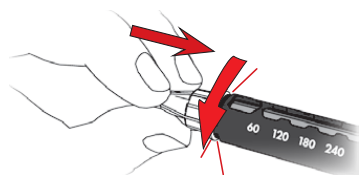
Attaching the pen needle:



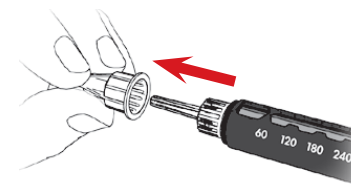
1. Pull off the pen cap.



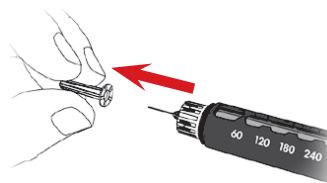
2. Pull off the protective foil on the pen needle



3. Push the pen needle onto the Ansulin[™] R D-Pen keeping it straight & screw it to attach.

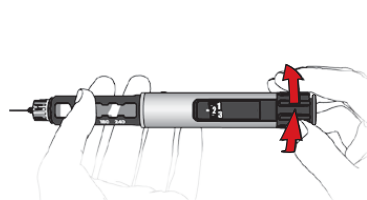


4. Pull off the outer pen needle cap and keep for use after the injection.



5. Pull off the inner pen needle cap.

Priming or functional test:



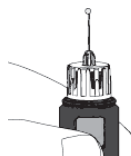
6. Prior to the first injection, remove air bubbles from the cartridge for accurate dosing. Select a dose of 2 units by turning the dose knob clockwise (2 clicks).



8. Press the push button all the way until number '0' is visible in the display window.



7. Hold the pen in an upright position (pen needle pointing up). Tap slightly with the finger on the cartridge holder to allow potential air bubbles within the cartridge to rise up.



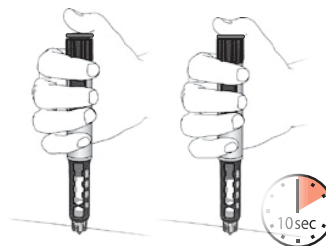
9. Check whether a droplet of liquid shows at the tip of the pen needle. If no drops appear repeat steps 6-9 (priming or functional test) until a drop appears.

Setting the dose:



10. Turn the dose knob clockwise until the prescribed dose aligns with the dose indicator in the display window. If necessary, the dose can be corrected by turning the dose knob counter-clockwise.

Injection



11. Hold the pen so that the display window is visible during the injection. Insert the pen needle into the skin and press the push button all the way in until a hard stop is felt and the number '0' is visible in the display window. Check if the display is at the "0" position.



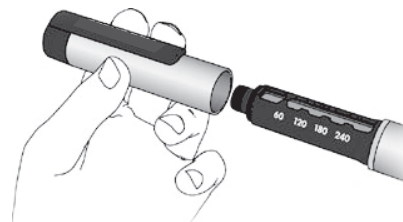
12. When the complete dose has been delivered, keep the push button pressed for another 10 seconds. Then slowly remove the pen from the injection site.

Disposal of the pen needle:



13. Replace the outer needle cap carefully. Unscrew the pen needle counter-clockwise and dispose of the pen needle safely in bin.

Pen cap mounting:

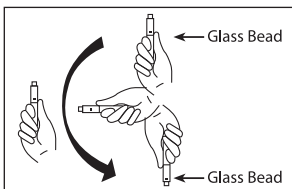


14. Firmly attach the pen cap to the pen for protection between injections.

Dosage & Administration

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.



Gently turn the pen upside down (see the picture) for 8-10 times until the insulin in the cartridge becomes uniformly mixed suspension.

Use in 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 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.

Warning & 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.

Contraindication

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

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.

Overdose

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 **Ansulin® D-Pen** in use can be kept under the room temperature (below 30°C) for 28 days.

How supplied

Ansulin® R D-Pen: Each box contains 03 Disposable Pens of 3mL **Ansulin® R D-Pen**.

Ansulin® 30/70 D-Pen: Each box contains 03 Disposable Pens of 3mL **Ansulin® 30/70 D-Pen**.

For further information please contact: 01708 810 822

Manufactured by



SQUARE
PHARMACEUTICALS PLC.
Kaliakoir, Gazipur, Bangladesh