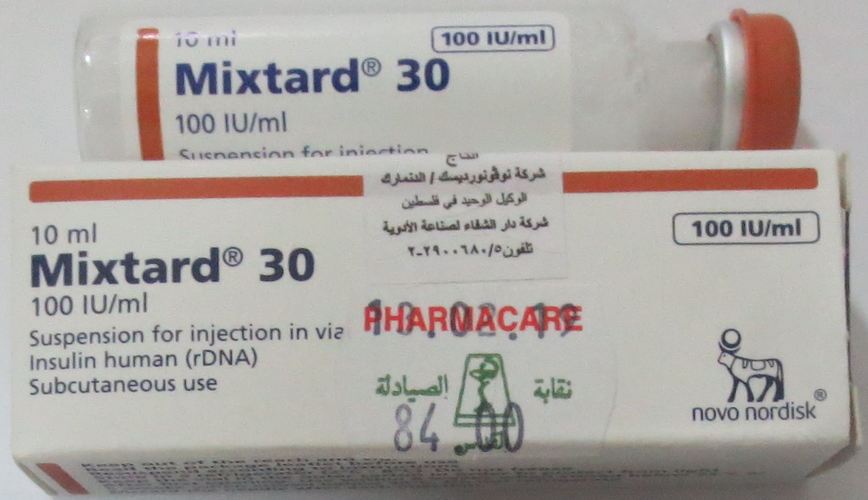


100 IU/ml

Mixtard® 30

Suspension for injection in vial.

Qualitative and quantitative composition

Insulin human, rDNA (produced by recombinant DNA technology in *Saccharomyces cerevisiae*).
1 ml contains 100 IU of insulin human.
1 vial contains 10 ml equivalent to 1,000 IU.
One IU (International Unit) corresponds to 0.035 mg of anhydrous human insulin.
Mixtard® is a mixture of dissolved insulin and isophane (NPH) insulin.
Mixtard® 30 consists of 30% dissolved insulin and 70% isophane insulin.

Pharmaceutical form

Suspension for injection in vial.
Cloudy, white, aqueous suspension.

Therapeutic indications

Treatment of diabetes mellitus.

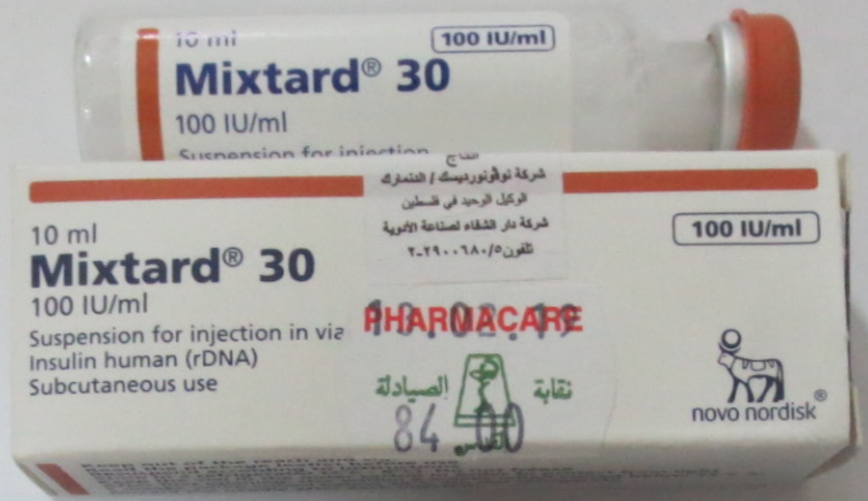
Posology and method of administration

Mixtard® is a dual-acting insulin. It is a biphasic formulation containing both fast-acting and long-acting insulin. Premixed insulin products are usually given once or twice daily when a rapid initial effect together with

As with any insulin therapy, injection site reactions may occur and include pain, redness, hives, inflammation, bruising, swelling and itching. Continuous rotation of the injection site within a given area may help to reduce or prevent these reactions. Reactions usually resolve in a few days to a few weeks. On rare occasions, injection site reactions may require discontinuation of Mixtard®.
Before travelling between different time zones, the patient should be advised to consult the physician, since this may mean that the patient has to take insulin and meals at different times.
Insulin suspensions are not to be used in insulin infusion pumps.

Combination of thiazolidinediones and insulin medicinal products

Cases of congestive heart failure have been reported when thiazolidinediones were used in combination with insulin, especially in patients with risk factors for development of congestive heart failure. This should be kept in mind if treatment with the combination of thiazolidinediones and insulin medicinal products is considered. If the combination is used, patients should be observed for signs and symptoms of congestive heart failure, weight gain and oedema. Thiazolidinediones should be discontinued if any deterioration in cardiac symptoms occurs.



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