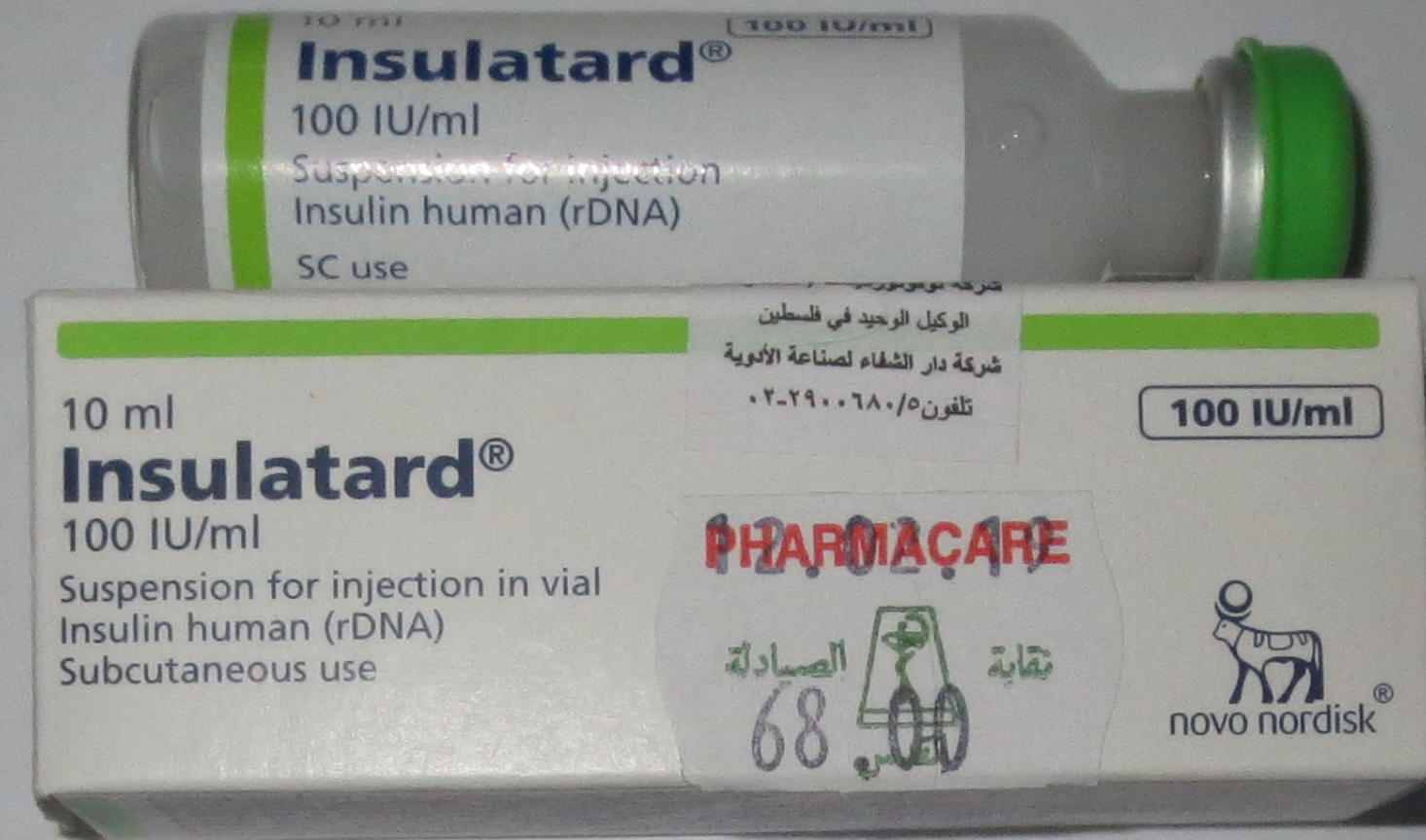




100 IU/ml

## Insulatard®

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.

Insulatard® is a suspension of isophane (NPH) insulin.

### Pharmaceutical form

Suspension for injection in vial.

Cloudy, white, aqueous suspension.

### Therapeutic indications

Treatment of diabetes mellitus.

### Posology and method of administration

Insulatard® is a long-acting insulin and may be used alone or in combination with fast or rapid-acting insulin products.

### Dosage

Dosage is individual and determined in accordance with the needs of the patient. The individual insulin requirement is usually between 0.3 and 1.0 IU/kg/day.

### 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.

### Interaction with other medicinal products and other forms of interaction

A number of medicinal products are known to interact with the glucose metabolism.

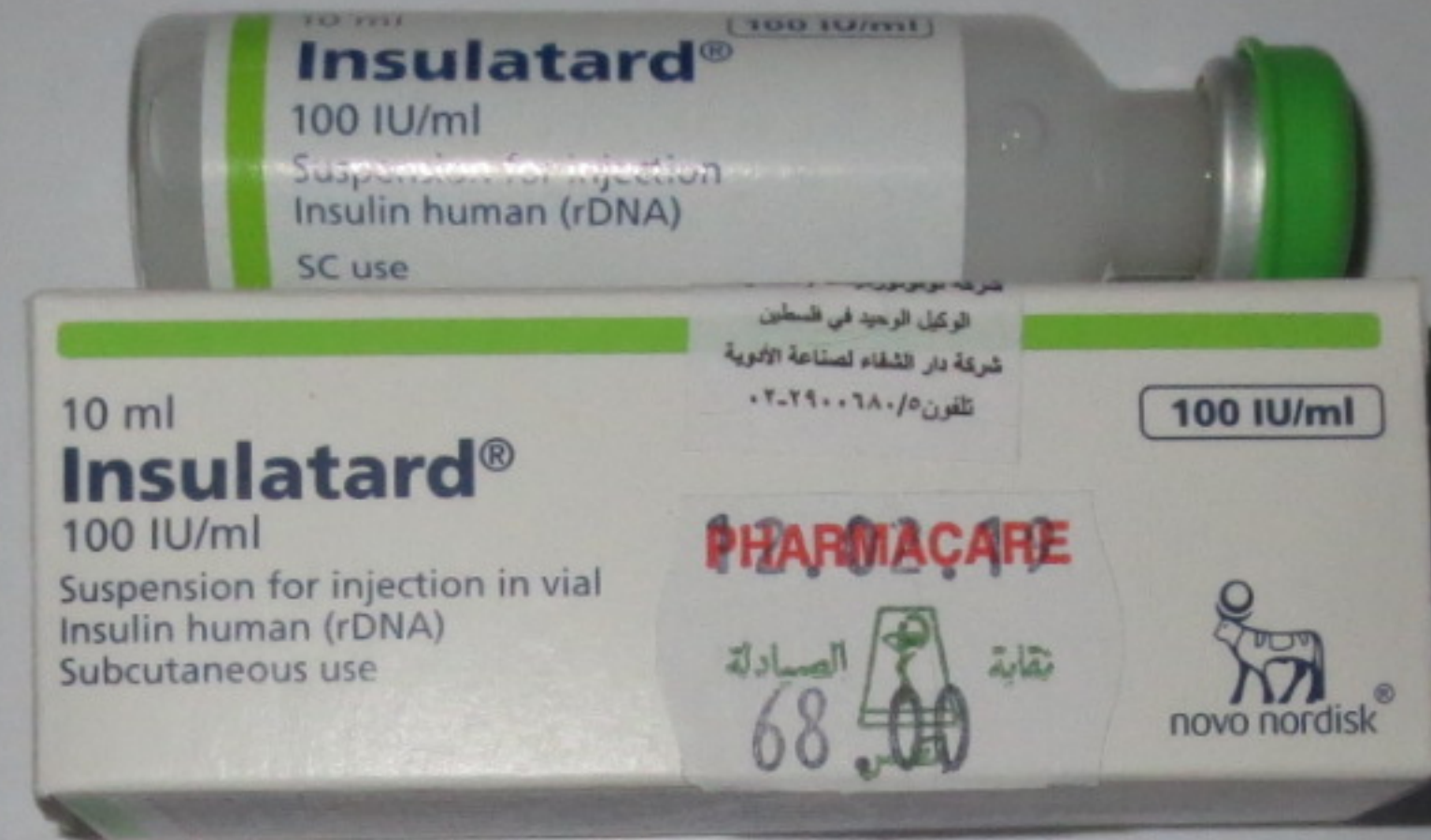
### The following substances may reduce the patient's insulin requirement:

Oral anti-diabetic products, monoamine oxidase inhibitors (MAOI), non-selective beta-blocking agents, angiotensin converting enzyme (ACE) inhibitors, salicylates, anabolic steroids and sulphonamides.

### The following substances may increase the patient's insulin requirement:

Oral contraceptives, thiazides, glucocorticoids, thyroid hormones, sympathomimetics, growth hormone and danazol.





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