

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

Abridged Prescribing Information

INSUTAGE® R (Insulin Injection Soluble I.P. 100 IU/ml)

INSUTAGE® 30/70 (Biphasic Isophane Insulin Injection I.P.100 IU/ml)

100 IU/mL in 3mL Cartridges for use with MyStar® pen.

COMPOSITION

INSUTAGE® R is Insulin Injection Soluble IP 100 IU/ml

INSUTAGE® 30/70 is Biphasic Isophane Insulin Suspension (30% as Soluble Insulin Injection and 70% as Isophane Insulin Injection)

THERAPEUTIC INDICATIONS: for the treatment of patient with diabetes mellitus, maintain normal glucose homeostasis in patient with diabetes.

DOSAGE AND ADMINISTRATION: The dosage is determined by the physician according to the needs of the patient. INSUTAGE® R cartridge is generally administered 15-30 minutes before a meal, and INSUTAGE® 30/70 cartridges are usually administered 30-60 minutes before a meal.

SAFETY-RELATED INFORMATION

Contraindications: Hypersensitivity to the active or to any of the excipients; Intravenous administration of insulin suspensions and Hypoglycemia (low blood sugar)

Precautions: Any change of insulin cartridge should be made with caution and only under medical supervision. Dose adjustments may be required, and appropriate testing should be conducted prior to initiation of INSUTAGE® cartridge treatment in patients who have previously developed generalized allergic reactions to insulin preparations. The most frequent adverse reactions experienced by insulin users is hypoglycemia (Low blood sugar), the patient should learn to monitor the level of glucose in blood and urine frequently to familiarize themselves, if uncertain with the symptoms of hypoglycemia. Cases of cardiac failure have been reported with the usage of thiazolidinediones in combination with insulin, especially in patients with multiple risk factors predisposing to cardiac heart failure. If treatment in combination of insulin and pioglitazone is considered patients should be observed for signs and symptoms of heart failure, weight gain and edema. Discontinue thiazolidinediones, if any deterioration in cardiac symptoms occurs. Avoid sharing of needles or syringes between patients in order to avoid transmission of blood-borne pathogens. The cartridges should be used in conjunction with MyStar® pen and should not be used with any other reusable pen as the dosing accuracy has not been established with other pens.

Pregnancy and Lactation: Patients who are pregnant or planning to become pregnant should consult the doctor, it is essential to maintain continuous good control of glycaemia among diabetics requiring insulin throughout the pregnancy as hyperglycemia may harm the foetus. The dosages of INSUTAGE® may need to be adjusted in lactating women.

Adverse Reactions: Hypoglycemia is the most frequent undesirable effect of insulin. Human insulin can cause a shift in potassium leading to hypokalemia. Other adverse events that occasionally occur during treatment with biosynthetic insulin are allergy to insulin, insulin resistance, post-insulin Lipodystrophy. Localized cutaneous amyloidosis at the injection site has occurred with insulins. Human insulin may cause sodium retention and edema.

For full prescribing information please write to Sanofi India Ltd., Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072

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