

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

INSUMAN<sup>®</sup> RAPID (Human Insulin Injection I.P.)  
INSUMAN<sup>®</sup> COMB 25 (Biphasic Isophane Insulin Injection I.P.)  
INSUMAN<sup>®</sup> COMB 50 (Biphasic Isophane Insulin Injection I.P.)  
in 100 IU/mL in 3mL Cartridges for use with AllStar.

### **Abridged Prescribing Information**

#### **COMPOSITION**

**Insuman Rapid** is a neutral insulin solution (regular insulin)

**Insuman Mixed: Insuman Comb 25** is biphasic isophane insulin suspension (25% dissolved insulin+75% crystalline protamine insulin) and **Insuman Comb 50** is biphasic isophane insulin suspension (50% dissolved insulin+50%crystalline protamine insulin).

**THERAPEUTIC INDICATIONS:** Diabetes mellitus Type I or Type II.

**DOSAGE AND ADMINISTRATION:** There are no fixed rules for insulin dosage. However average insulin requirement is often 0.5 to 1.0 IU per kg body weight per day. Basal metabolic requirement is 40% to 60% of total daily requirement. The desired blood glucose levels, the insulin preparations to be used and the insulin dosage (doses and timing) must be determined and adjusted individually to suit the patient's diet, physical activity and life style.

#### **SAFETY-RELATED INFORMATION**

**Contraindications:** Hypersensitivity to the active or to any of the excipients. Insuman Rapid must not be used in external or implanted insulin pumps or in peristaltic pumps with silicone tubing; Insuman Mixed must not be administered intravenously and must not be used in infusion pump or external/implanted insulin pumps.

**Precautions:** In patients with renal impairment, hepatic impairment or elderly, there may be a steady decrease in insulin requirements. In case of insufficient glucose control or a tendency to hyper or hypoglycaemic episodes, the patient's adherence to the prescribed treatment regimen, injection sites and proper injection technique and all other relevant factors must be reviewed before dose adjustment is considered. Hypoglycemia may occur if the insulin dose is too high in relation to requirement. Intercurrent illness requires metabolic monitoring. The Insuman cartridges should only be used with AllStar and should not be used with any other reusable pen as the dosing accuracy has only been established with the above pens.

**Pregnancy and Lactation:** No experience with the use of Insuman in pregnant women. Insulin does not cross the placental barrier. Lactating women may require adjustments in insulin dose and diet.

**Adverse Reactions:** Hypoglycemia is the most frequent undesirable effect of insulin. Medication errors have been reported in which other Insuman formulations or other insulins have been accidentally administered. Insulin may cause oedema if previously poor metabolic control is improved by intensified insulin therapy. Mild reactions at injection site may occur commonly.

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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**Source:** Insulin Human CCDS version 7 dated 23<sup>rd</sup> April 2013