

## **Prescribing Information**

**Insuman® (insulin human).** Please refer to **Summary of Product Characteristics prior to use of Insuman.** Insuman Basal, Comb 15, Comb 25, Comb 50 and Rapid cartridges, in addition to the Insuman Basal and Comb 25 Solostar pens each contain 300 IU of insulin human in 3ml, equivalent to 10.5mg. Insuman Basal and Comb 25 vials contain 500 IU of insulin human in 5ml, equivalent to 17.5mg. Insuman Rapid contains neutral insulin solution (regular insulin). Insuman Basal contains isophane insulin suspension. Insuman Comb 15, 25 and 50 contain 15% regular and 85% isophane, 25% regular and 75% isophane, and 50% regular and 50% isophane insulin, respectively. **Indications:** Diabetes mellitus. Insuman Rapid cartridges are also suitable for the treatment of hyperglycaemic coma, ketoacidosis, and for achieving pre-, intra- and post-operative stabilisation. **Dosage and administration:** Insulin doses and timings should be determined individually. There are no fixed rules for insulin dosage. Average insulin requirement is often 0.5 to 1.0 IU/kg body weight/day. Basal metabolic requirement is 40% to 60% of total daily requirement. Insuman should be injected subcutaneously: Insuman Rapid should be injected 15 to 20 minutes before a meal; Insuman Basal should be injected 45 to 60 minutes before a meal; Insuman Comb 15 and 25 should be injected 30 to 45 minutes before a meal; Insuman Comb 50 should be injected 20 to 30 minutes before a meal. Insuman Rapid cartridges may also be administered intravenously under close medical supervision. Close metabolic monitoring is recommended during, and for a period after, transition from other insulins to Insuman. Dose and timing of other antidiabetic medicines may need to be adjusted. Dose adjustments may also be required if the patient's weight or lifestyle changes, the timing of insulin dose is changed or other circumstances arise that increase susceptibility to hypo- or hyperglycaemia. Insulin requirements may be diminished in the elderly or patients with renal or hepatic impairment. **Contra-indications:** Hypersensitivity to human insulin or to any excipients. IV administration contraindicated in all preparations except Insuman Rapid. Insuman Basal contraindicated in infusion pumps or external or implanted insulin pumps. Insuman Rapid must not be used in external or implanted insulin pumps or in peristaltic pumps with silicone tubing. **Precautions and warnings:** Patients hypersensitive to Insuman Rapid, Basal or Comb 15, 25 or 50 for whom no better tolerated preparation is available must only continue treatment under close medical supervision, in conjunction with anti-allergic treatment if necessary. In patients allergic to animal insulin, intradermal skin testing is recommended prior to initiation. Hypoglycaemia may occur. Particular caution should be exercised, and intensified blood monitoring is advisable for patients in whom hypoglycaemic episodes might be of clinical relevance and in those where dose adjustments may be required. Warning signs of hypoglycaemia may be changed, less pronounced or absent in certain risk groups, potentially resulting in severe hypoglycaemia and loss of consciousness. Risk groups include patients in whom glycaemic control is markedly improved, hypoglycaemia develops gradually, an autonomic neuropathy is present, or in elderly patients. Intensified metabolic monitoring is necessary during intercurrent illness. Cases of cardiac failure have been reported when pioglitazone was used in combination with insulin, especially in patients with risk factors for development of cardiac heart failure. Patients should be observed for signs and symptoms of heart failure, weight gain and oedema. Pioglitazone should be discontinued if any deterioration in cardiac symptoms occurs. **Pregnancy and lactation:** There is no clinical data on the use of Insuman in pregnant women. Insuman can be used during breast feeding. **Adverse Reactions:** Hypoglycaemia is the most common reaction. Prolonged or severe hypoglycaemia may be life-threatening. Severe hypoglycaemic attacks, especially if recurrent, may lead to neurological damage. Common: oedema, injection site reactions. Uncommon: shock, injection site urticaria. Immediate type allergic reactions to insulin or to the excipients may

be life-threatening (hypotension, angioneurotic oedema, bronchospasm, generalised skin reactions). Insulin administration may cause insulin antibodies to form and may, in rare cases, necessitate adjustment of the insulin dose.

<b>Product</b>	<b>Pack</b>	<b>NHS Price</b>	<b>MA Number</b>
Insuman Rapid	5 cartridges of 3ml	£17.50	EU/1/97/030/030
Insuman Basal	1 vial of 5ml:	£5.61	EU/1/97/030/033
Insuman Basal	5 cartridges of 3ml	£17.50	EU/1/97/030/035
Insuman Basal	5 SoloSTAR pens of 3ml	£19.80	EU/1/97/030/148
Insuman Comb 15	5 cartridges of 3ml	£17.50	EU/1/97/030/040
Insuman Comb 25	1 vial of 5ml	£5.61	EU/1/97/030/043
Insuman Comb 25	5 cartridges of 3ml	£17.50	EU/1/97/030/045
Insuman Comb 25	5 SoloSTAR pens of 3ml	£19.80	EU/1/97/030/160
Insuman Comb 50	5 cartridges of 3ml	£17.50	EU/1/97/030/050

**Legal category:** POM. **MA holder:** Sanofi Aventis Deutschland GmbH, D-65926 Frankfurt am Main, Germany. **Full prescribing information is available from:** Sanofi, One Onslow Street, Guildford, Surrey, GU1 4YS. Tel: 0845 372 7101. **Date of Revision:** October 2014

**Adverse events should be reported. Reporting forms and information can be found at [www.yellowcard.mhra.gov.uk](http://www.yellowcard.mhra.gov.uk). Adverse events should also be reported to the Sanofi drug safety department on 01483 554242.**