25 July 2013
EMA/CHMP/435143/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1]

Insuman Implantable

Insulin human

On 25 July 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the addition of a new formulation to the marketing authorisation of the medicinal product Insuman. The new formulation, Insuman Implantable, is an insulin solution for infusion (400 IU/ml) that is delivered into the intra-peritoneal cavity via an implantable pump device (MiniMed). It has been developed as a replacement for another insulin product called Insuplant, which is no longer manufactured.

The marketing authorisation holder for Insuman is Sanofi-Aventis Deutschland GmbH. The CHMP recommendation will now be forwarded to the European Commission, which will issue a legally binding decision.

Insuman Implantable is intended for the treatment of type 1 diabetes mellitus that cannot be controlled with subcutaneous insulin (including pump) therapy, presenting with frequent, otherwise unexplained severe hyper- and/or hypo-glycaemia.

Prescription of Insuman Implantable will be restricted to centres certified by Medtronic (the manufacturer of the MiniMed pump) as having had their personnel adequate trained in the use of the pump with Insuman Implantable. Use of Insuman Implantable should be supervised by a physician experienced in diabetes and in the use of intraperitoneal insulin.

The benefits with Insuman Implantable are its ability to improve glycaemic control in otherwise difficult to treat adult patients with type 1 diabetes mellitus. The most common side effects related to the insulin are hyperglycaemia, hypoglycaemia, hypoglycaemic seizure, hypoglycaemic unconsciousness, oedema and hypoglycaemic coma. The most common side effects and product technical complaints observed with the delivery system are implant site infection, abdominal pain, umbilical hernia, skin erosion at pump implantation site, device occlusion, catheter site pain, medical device change due to device malfunction and device blockage.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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A pharmacovigilance plan for Insuman Implantable will be implemented as part of the marketing authorisation.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.