HAUTE AUTORITÉ DE SANTÉ

DIABETOLOGY
New medicinal product
October 2014

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

INSUMAN IMPLANTABLE (insulin human), antidiabetic

No added clinical value demonstrated in the management of patients with type 1 diabetes

Main points

- INSUMAN IMPLANTABLE has a Marketing Authorisation in the treatment of adult patients with type 1 diabetes who are not controlled by insulin administered subcutaneously (including via a pump) and displaying severe, frequent or unexplained hyperglycaemic and/or hypoglycaemic episodes.
- It has to be administered exclusively with the Medtronic MiniMed implantable insulin pump system fitted with an intraperitoneal catheter.
- The available data do not allow an assessment to be made of its effect in patients with type 1 diabetes in whom intensive, subcutaneous insulin therapy has failed.
- This is a treatment of last resort.
- The most common adverse events were hyperglycaemic episodes, hypoglycaemic loss of consciousness and pump blockages. Adverse events linked to the device (infectious or mechanical complications) may lead to the explantation of all or part of the pump system.

Therapeutic use

In type 1 diabetic patients who have not achieved the recommended glycaemic targets (HbA1c between 6.5 and 7.5%) with conventional insulin therapy, intensive insulin therapy is recommended in the form of multiple, daily, subcutaneous injections (at least four a day), or in the form of the continuous infusion of insulin via an external pump.

Role of the medicinal product in the therapeutic strategy

Insulin therapy via an implantable pump with an intraperitoneal catheter is a treatment of last resort in adult patients with type 1 diabetes in whom, despite training and intensified medical monitoring, intensive, subcutaneous insulin therapy (external pump or daily multiple injections) has failed and who have severe, common or unexplained hyperglycaemic and/or hypoglycaemic episodes

Clinical data

- INSUMAN IMPLANTABLE has demonstrated its non-inferiority in terms of the reduction in HbA1c by comparison with porcine insulin (INSUPLANT) in a phase III study that included 169 patients who had already been implanted and treated with INSUPLANT and had a mean HbA1c of 7.7%. The variety of the implanted pumps, and the characteristics of the patients included raise the problem of the transferability of these data.
- The phase III study that evaluated the successive administration of INSUPLANT then INSUMAN IMPLANTABLE given by the intraperitoneal route with intensive insulin therapy does not allow any conclusion to be drawn about the superiority of INSUMAN IMPLANTABLE over the insulin therapy.
- Non-inferiority was not demonstrated in terms of the occurrence of severe hypoglycaemic episodes for INSUMAN IMPLANTABLE by comparison with intensive insulin therapy.
- The most common adverse events were hyperglycaemic episodes, hypoglycaemic loss of consciousness and pump blockages. The adverse events, such as skin infections or abrasions in connection with the device led to the explantation of all or part of the pump system.

Prescribing conditions

Medicinal product reserved for hospital use

Benefit of the medicinal product

- The actual benefit* of INSUMAN IMPLANTABLE is substantial.
- Given, firstly, the inclusion in the clinical studies of a population different to the population of the indication, which did not allow an evaluation of the effect of the proprietary medicinal product in type 1 diabetic patients in whom intensive subcutaneous insulin therapy had failed and, secondly, the explantations of all or part of the administration system on account of infectious or mechanical complications associated with this type of treatment, INSUMAN IMPLANTABLE does not provide any clinical added value** (CAV V, none) in type 1 diabetic patients in whom intensive subcutaneous insulin therapy (daily multiple injections or external pump) has failed and who have severe, common or unexplained hyperglycaemic and/or hypoglycaemic episodes.
- Recommends inclusion on the list of reimbursable products for hospital use.

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This document was created on the basis of the Transparency Committee Opinion of 22 October 2014 (CT-13127) and is available at **www.has-sante.fr**

[i] * The actual benefit (AB) of a proprietary medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the AB, which can be substantial, moderate, low or insufficient for reimbursement by the National Health Insurance

** The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV means "no clinical added value".