HAUTE AUTORITÉ DE SANTÉ

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

MENOTROPHINE LG (gonadotrophin), ovulation stimulant

No clinical benefit demonstrated when compared with MENOPUR in the induction of ovulation and in controlled ovarian hyperstimulation

Main points

- MENOTROPHINE LG has Marketing Authorisation in the induction of ovulation in the context of amenorrhoea or anovulation in women who have been unresponsive to treatment with clomiphene citrate and in controlled ovarian hyperstimulation to trigger the development of multiple follicles in the context of assisted reproductive technology treatments such as in-vitro fertilisation.
- There are no data supporting the clinical superiority of MENOTROPHINE LG over MENOPUR.

Therapeutic use

Products containing human FSH are part of the strategies for medical management of infertility. The fact that around half of couples who do not conceive after 1 year will do so the next year must be considered before resorting to these treatments.

Role of the medicinal product in the therapeutic strategy

MENOTROPHINE LG is a first-line treatment for controlled ovarian hyperstimulation to trigger the development of multiple follicles in the context of assisted reproductive technology treatments.

It is a second-line treatment for the induction of ovulation in anovulatory patients (including those with polycystic ovary syndrome) after the failure of or intolerance to clomiphene citrate.

Clinical data

- Two randomised, single-blind, non-inferiority studies have compared the efficacy of MENOTROPHINE LG with that of MENOPUR (clinically relevant comparator) in controlled ovarian hyperstimulation in the course of IVF cycles. The primary efficacy endpoint was the number of oocytes retrieved by puncture.
  - In one study, MENOTROPHINE LG was statistically more effective than MENOPUR in relation to this criterion. Nevertheless, it should be noted that the rates of biochemical and clinical pregnancy, labour and live births observed in this study do not support MENOTROPHINE LG having clinically relevant superiority over MENOPUR.
  - The second concluded that MENOTROPHINE LG was not inferior to MENOPUR in terms of the number of oocytes retrieved by puncture. The rates of biochemical and clinical pregnancy per cycle were comparable under the two treatments.
- In one study, the most common adverse events considered to be treatment-related were gastrointestinal disorders: tension, abdominal pain, nausea (20.7% in each group), nervous system disorders: dizziness, headaches (18.5% in the MENOTROPHINE LG group versus 8.9% in the MENOPUR group), general disorders: fatigue or malaise (10.4% versus 8.9%), reproductive system disorders: hyperstimulation syndrome, pelvic pain, uterine spasms (8.2% versus 8.9%) including 3% versus 2.2% hyperstimulations.
- The serious adverse events considered to be treatment-related were one case of lower abdominal pain, one ovarian hyperstimularion, and one ovarian torsion in the MENOTROPHINE group and one ovarian hyperstimulation in the MENOPUR group. The pregnancy monitoring data and the data relating to the newborns do not allow any conclusions to be drawn about differences between the treatment groups in relation to safety.
- In the other study, treatment-related adverse events occurred in 3 patients (3.8%) in the MENOTROPHINE group (2 cases of ovarian hyperstimulation, one of them serious, and one ovarian cyst) and none in the MENOPUR group.

Special prescribing conditions

- Medicinal product requiring special monitoring during treatment.
- Prescription restricted to doctors specialising in gynaecology and/or gynaecology-obstetrics and/or endocrinology and metabolism.

Benefit of the medicinal product

- The actual benefit* of MENOTROPHINE LG is substantial.
- The efficacy data do not support a clinically relevant superiority of MENOTROPHINE LG; MENOTROPHINE LG therefore does not provide clinical added value** (CAV V) relative to MENOPUR.
- Recommends inclusion on the list of reimbursable products for supply by pharmacists and for hospital use.

HAUTE AUTORITÉ DE SANTÉ

This document was created on the basis of the Transparency Committee Opinion of 02 December 2015 (CT-14594) and is available at **www.has-sante.fr**

[i]

[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 for hospital use.

** 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".