HAUTE AUTORITÉ DE SANTÉ

GYNAECOLOGY
Update
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BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

MIFFEE (mifepristone), progesterone receptor modulator

No new clinical efficacy data.
Data on its prescribing conditions, efficacy and safety must be provided within a maximum of one year.

Main points

- MIFFEE has marketing authorisation for medical termination of developing intrauterine pregnancy, in sequential use with a prostaglandin analogue, up to 63 days of amenorrhoea.
- The data provided by the pharmaceutical company after 2 years of marketing do not answer the Transparency Committee's questions about prescribing methods for MIFFEE (dose administered) and the associated prostaglandin (type, dose administered and route of administration) in France.

Therapeutic use

- In France, the medical method for voluntary termination of pregnancy currently combines an antiprogestogen (mifepristone) and a prostaglandin. It is possible up to 9 weeks of amenorrhoea (WA).
- The recommended sequences of treatment are:
  For pregnancies of less than 7 WA (maximum 49 days of amenorrhoea),
  a single oral dose of 600 mg mifepristone (MIFEGYNE), followed 36 to 48 h later by administration of a prostaglandin analogue: 400 µg misoprostol orally or 1 mg gemeprost vaginally;
  or a single oral dose of 200 mg mifepristone (MIFEGYNE or MIFFEE), followed 36 to 48 h later by vaginal administration of a prostaglandin analogue: 1 mg of gemeprost.
  For pregnancies of 7 to 9 WA (50 to 63 days of amenorrhoea),
  a single oral dose of 600 mg mifepristone (MIFEGYNE), followed 36 to 48 h later by vaginal administration of a prostaglandin analogue: 1 mg of gemeprost.
  or a single oral dose of 200 mg mifepristone (MIFEGYNE or MIFFEE), followed 36 to 48 h later by vaginal administration of a prostaglandin analogue: 1 mg of gemeprost.
- **Role of the medicinal product in the therapeutic strategy**
  MIFFEE 200 mg can be used as a first-line option for the voluntary termination of pregnancy when prescribed in accordance with its marketing authorisation, i.e. as a single dose of 200 mg and only in combination with gemeprost.

Clinical data

- The company has not provided any new clinical efficacy data.
- The safety data provided do not change the known safety profile of this proprietary medicinal product.
- The data provided by the pharmaceutical company do not answer the Transparency Committee's questions about how MIFFEE and the associated prostaglandin are prescribed in France. In light of data showing misuse in some European countries and bearing the existing alternatives in mind, this medicine is not expected to increase the success rate of voluntary terminations of pregnancy or to be better tolerated. Consequently, a negative impact on public health cannot be ruled out.

Special prescribing conditions

- Outside healthcare organisations: medicinal product reserved for professional use by authorised centres and doctors in accordance with article L. 2212-1 of the French Public Health Code.

Benefit of the medicinal product

- The actual clinical benefit* of MIFFEE is substantial in its marketing authorisation indication, subject to the provision of French data on its prescribing conditions, efficacy and safety within a maximum period of 12 months.
- The Committee recommends continued inclusion on the list of reimbursable products for hospital use, within its indication and at the dosages in the marketing authorisation. This favourable opinion is conditional on a study of the prescribing conditions, efficacy and safety of MIFFEE in France.

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This document was created on the basis of the Transparency Committee Opinion of 08 February 2017 (CT-15425) and is available at **www.has-sante.fr**

* The actual clinical benefit (ACB) 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 ACB, 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”.