misoprostol
MISOONE 400 µg scored tablets

New indication

Key points

Favourable opinion for reimbursement in cervix uteri preparation prior to surgical termination of pregnancy during the first trimester.

What therapeutic improvement?

No clinical added value in the therapeutic strategy.
Role in the care pathway?

In all cases where possible, women must be able to choose the method of voluntary termination of pregnancy (elective abortion), whether medical or surgical, and receive detailed information.

A surgical termination of pregnancy consists of dilation of the cervix and aspiration of the uterine contents under general or local anaesthetic. This method may be offered at any time up to 12 weeks of pregnancy (14 weeks of amenorrhoea) and if the medical method fails. However, the surgical method will be favoured to the medical method from 7 weeks of pregnancy (9 weeks of amenorrhoea).

In a surgical termination, medical or mechanical preparation of the cervix is recommended to facilitate dilation and reduce its complications:

- Medical preparation is based on the use of an oral antiprogesterone, MIFEGYNE 200 mg (mifepristone) 36 to 48 hours before aspiration, or an oral prostaglandin, GYMISO 200 µg (misoprostol) 3 to 4 hours before aspiration, or CERVAGEME 1 mg (gemeprost) by the vaginal route 3 hours before aspiration.
- Mechanical preparation of the cervix is based on the use of osmotic dilators (laminaria) or synthetic mechanical dilators.

Role of the medicinal product in the care pathway

MISOONE 400 µg (misoprostol) scored tablets are a therapeutic alternative in the medical preparation of the cervix before aspiration of the uterine contents in the context of surgical termination of pregnancy.

Special recommendations

The Committee reiterates that, in accordance with the SPC, MISOONE 400 µg (misoprostol) scored tablets are administered as a single oral dose 3 to 4 hours before surgical aspiration.
01 COMMITTEE’S CONCLUSIONS

01.1 Clinical benefit

➤ Voluntary termination of pregnancy (abortion) is a procedure that should be performed in a setting ensuring the safety of the woman undergoing it.
➤ MISOONE 400 µg (misoprostol) is used in the context of surgical voluntary termination of pregnancy.
➤ The efficacy/adverse effects ratio of MISOONE (misoprostol) is high.
➤ The medicinal products MIFEGYNE 200 mg (mifepristone), GYMISO 200 µg (misoprostol) and CERVAGEME 1 mg (gemeprost), as well as osmotic or mechanical dilators, are therapeutic alternatives to MISOONE 400 µg (misoprostol).
➤ MISOONE 400 µg (misoprostol) is a therapeutic alternative in the medical preparation of the cervix before aspiration of the uterine contents in the context of surgical termination of pregnancy.

Public health impact

Considering:
- the incidence of surgical voluntary terminations of pregnancy,
- the met medical need,
- the lack of elements supporting the absence of a deterioration in the care and/or life pathway in the absence of robust quality of life data,
- the lack of demonstrated impact on the organisation of care (hospitalisation, AEs),
- the lack of additional response to the identified need,
MISOONE 400 µg (misoprostol), a new proprietary medicinal product containing misoprostol, is unlikely to have an additional impact on public health compared to the alternatives already available.

Given all these elements, the Committee deems that the clinical benefit of MISOONE 400 µg (misoprostol) is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion in the hospital formulary list of reimbursed proprietary medicinal products approved for use in “cervix uteri preparation prior to surgical termination of pregnancy during the first trimester” and at the MA dosage.

01.2 Clinical Added Value

Considering:
- the known efficacy and safety profile of oral misoprostol 400 µg;
- the lack of comparative data;
- the medical need currently met by another medicinal product containing misoprostol;
the Transparency Committee considers that MISOONE 400 µg (misoprostol) scored tablets provide no clinical added value (CAV V) in the management strategy for surgical voluntary termination of pregnancy.