

SUMMARY

misoprostol

**GYMISO 200 micrograms
tablets**

Inclusion on list: First listing

Range supplement

Adopted by the Transparency Committee on 28 August 2024

Summary of opinion

Favourable opinion for reimbursement in the:

“Medical termination of early pregnancy of less than 49 days of amenorrhea, in combination with mifepristone.

Preparation of the cervix for surgical termination of pregnancy in the first trimester.”

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Transparency Committee's conclusions

Clinical Benefit

Medical termination of early pregnancy of less than 49 days of amenorrhea, in combination with mifepristone

- ➔ Medical termination of pregnancy is a regulated medical procedure that requires strict monitoring.
- ➔ The efficacy/adverse effects ratio of this proprietary medicinal product is high.
- ➔ This is a first-line treatment in combination with mifepristone.

➔ **Public health benefit**

GYMISO (misoprostol) is unlikely to have an additional impact on public health.

The Committee deems that the clinical benefit of GYMISO 200 micrograms (misoprostol) is substantial.

Preparation of the cervix for surgical termination of pregnancy in the first trimester

- ➔ Medical termination of pregnancy is a regulated medical procedure that requires strict monitoring.
- ➔ The efficacy/adverse effects ratio of this proprietary medicinal product is high.
- ➔ This product is a first-line treatment.

➔ **Public health benefit**

GYMISO (misoprostol) is unlikely to have an additional impact on public health.

The Committee deems that the clinical benefit of GYMISO 200 micrograms (misoprostol) is substantial.

The Committee issues a favourable opinion for inclusion in the list of covered drugs for inpatients approved for use in the indications and at the MA dosages.