HAUTE AUTORITÉ DE SANTÉ

OBSTETRICS
Update
June 2018

TRANSPARENCY COMMITTEE OPINION SUMMARY

METHERGIN (methylergometrine), oxytocic

Insufficient clinical benefit to justify reimbursement in the management of delivery in the event of obstetrical emergency, due to its lack of role in the therapeutic strategy.

High clinical benefit for performing the METHERGIN test.

Main points

- METHERGIN has been granted marketing authorisation:
  - in obstetrics, for the management of delivery in the event of obstetrical emergency (delivery and post-partum haemorrhage), following caesarian section, curettage and abortion by suction or curettage, uterine subinvolution or atony, or after the expulsion stage.
  - in cardiology, when performing the METHERGIN test.
- METHERGIN is no longer mentioned in the French guidelines for the treatment of delivery and post-partum haemorrhages due to insufficient clinical benefit.
- Its clinical benefit remains high, however, in cardiology.

Therapeutic strategy

- Initial treatment for post-partum haemorrhages consists of artificial delivery or uterine exploration if the placenta has been expelled, combined with prophylactic antibiotic therapy, speculum-assisted birth canal examination, with appropriate analgesia and uterine massage.
  Medical treatment consists of oxytocin injection. If oxytocin is unable to stem bleeding, sulprostone administration, within 30 minutes of the diagnosis of post-partum haemorrhage, is recommended. This time may be shortened according to the severity of bleeding.
  Intrauterine balloon tamponade may be proposed if management with sulprostone fails and before resorting to invasive methods (surgery or arterial embolisation). Its use is left to the practitioner's discretion. It must not delay the implementation of invasive measures.
  Tranexamic acid may be of benefit in the management of delivery and post-partum haemorrhages in the event of persistent bleeding following sulprostone administration, even though its clinical benefit has not been demonstrated in an obstetrical context.
- Combining methylergometrine with sulprostone is contraindicated due to the existence of a risk of potentially fatal coronary vasoconstriction.
- The WHO and the International Federation of Gynaecology and Obstetrics recommend the use of ergometrine or methylergometrine for the treatment of post-partum haemorrhage in the event of unavailability or lack of response to oxytocin injection. These recommendations warn of the contraindications of ergot alkaloids in women with hypertension, heart disease, pre-eclampsia or eclampsia, due to their blood pressure-raising effect.
- **Role of the medicinal product in the therapeutic strategy**
  METHERGIN no longer has a role in the therapeutic strategy for the management of delivery in the event of obstetrical emergency.
  METHERGIN maintains its role in performing the vasospastic angina diagnostic test.

Clinical data

- The laboratory has not provided any new data concerning the therapeutic or diagnostic contribution of METHERGIN in the indications of its MA.
- The safety data are not such as to change its safety profile.

Benefit of the medicinal product

- The actual clinical benefit* of METHERGIN:
  - is insufficient in the management of delivery in the event of obstetrical emergency.
  - remains high in cardiology.
- Not approved for non-hospital pharmacy reimbursement or for hospital treatment within the obstetrical indication.
  Approved for non-hospital pharmacy reimbursement and for hospital treatment within the cardiac indication.

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This document was drafted on the basis of the Transparency Committee opinion dated 27 June 2018 (CT-14436) available at **www.has-sante.fr**

* The actual clinical benefit of a medicinal product (ACB) is its benefit particularly on the basis of its clinical performances and the severity of the disease treated. The HAS Transparency Committee assesses the ACB, which may be high, moderate, low, or insufficient for the medicinal product to be covered by public funding.

** The clinical added value (CAV) consists of the clinical improvement offered by a medicinal product compared to existing treatments. The HAS Transparency Committee assesses the CAV rating from I, major, to IV, minor. A CAV rating of V (equivalent to "no CAV") denotes a "lack of clinical improvement"