HAUTE AUTORITÉ DE SANTÉ

OBSTETRICS
Update
June 2018

TRANSPARENCY COMMITTEE OPINION SUMMARY

SALBUMOL (salbutamol), beta-2 agonist – labour inhibitor

Insufficient clinical benefit to justify its reimbursement in the short-term treatment of uncomplicated preterm labour and in emergency use in specific obstetric scenarios due to potentially severe maternal adverse cardiopulmonary effects

Main points

- SALBUMOL has MA for the short-term treatment of uncomplicated premature labour and for emergency use in specific obstetric scenarios.
- Betamimetic tocolytics are not recommended due to the existence of potentially severe maternal adverse cardiopulmonary effects.
- SALBUMOL no longer has a role in the therapeutic strategy

Therapeutic strategy

Preterm delivery remains the leading cause of neonatal mortality and morbidity due to sequelae. Tocolytic treatment aimed at delaying delivery by at least 48 hours makes it possible to initiate glucocorticoid therapy (foetal maturation) and organise the transfer of the mother and the child in utero to an intensive care unit.
The French National Association of Gynaecologists and Obstetricians recommends that betamimetics no longer be used for reducing uterine contractions.

Role of the medicinal product in the therapeutic strategy

SALBUMOL no longer has a role in the therapeutic strategy of scenarios requiring tocolysis.

Clinical data

Injectable salbutamol has demonstrated its efficacy in delaying delivery by 48 hours. However, its administration involves a risk of severe adverse cardiovascular effects: cardiac arrhythmia, myocardial ischemia, myocardial infarction or pulmonary oedema.

Benefit of the medicinal product

- The actual clinical benefit* of SALBUMOL 0.5 mg/1 ml, injectable solution is insufficient
- Not approved for non-hospital pharmacy reimbursement or for hospital treatment.

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This document was drafted on the basis of the Transparency Committee opinion dated 13 June 2018 (CT-15445) available at **www.has-sante.fr**

* The actual clinical benefit (ACB) of a medicinal product consists of 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.