



TRANSPARENCY COMMITTEE SUMMARY 5 JANUARY 2022

The legally binding text is the original French opinion version

sulprostone
NALADOR 500 µg lyophilisate for parenteral use
New indication

► Key points

Favourable opinion for reimbursement in the second-line uterotonic treatment of atonic postpartum haemorrhage resistant to first-line treatment with oxytocin.

► What therapeutic improvement?

No clinical added value.

► Role in the care pathway?

PPH is defined as blood loss ≥ 500 mL in the 24h following delivery and severe PPH is defined as blood loss ≥ 1000 mL. The incidence of PPH is around 5 to 10% of deliveries and PPH is severe in 2% of cases.

Uterine atony is the main cause of PPH. This involves abnormal uterine contraction during the third stage of labour, resulting in excessive bleeding from the placental insertion site, which excludes haemorrhages related to cervico-vaginal lesions, uterine rupture or coagulation abnormalities.

In the event of PPH following vaginal delivery, initial pharmacological treatment for PPH consists of an injection of oxytocin in addition to surgical techniques.

In the event of persistent PPH despite initial measures or in the event of PPH that is severe from the outset, the administration of sulprostone is recommended within 30 minutes of the diagnosis of PPH. This time may be shortened depending on the seriousness of bleeding.

The use of tranexamic acid is suggested in the event of PPH resistant to sulprostone. It should be administered as soon as possible, within 3 hours following the onset of PPH.

In the event of PPH following caesarean delivery, initial pharmacological treatment for PPH consists of an injection of oxytocin in addition to surgical techniques.

In the event of persistent PPH despite initial measures and/or in the event of haemodynamic disorders, the administration of sulprostone is recommended.

The use of tranexamic acid is suggested in the event of PPH resistant to sulprostone. It should be administered as soon as possible, within 3 hours following the onset of PPH.

In the postoperative period, if PPH persists (i.e. delayed PPH) and there is no hemoperitoneum or suspected vascular wound requiring urgent laparotomy, the initiation of a uterotonic agent (oxytocin or sulprostone depending on the severity) is necessary.

Role of NALADOR (sulprostone) in the care pathway:

Considering the available clinical data and good clinical practice guidelines, the Committee considers that NALADOR (sulprostone) 500 µg lyophilisate for parenteral use is a second-line uterotonic treatment of atonic postpartum haemorrhage resistant to first-line treatment with oxytocin.

COMMITTEE'S CONCLUSIONS

Considering all of this information and further to debate and voting, the Committee considers:

Clinical benefit

- ▶ Postpartum haemorrhage is the leading cause of severe maternal morbidity and can be life-threatening for the patient.
- ▶ The proprietary medicinal product NALADOR (sulprostone) is a curative medicinal product.
- ▶ The efficacy/adverse effects ratio is high.
- ▶ There are no alternatives at the same stage of the care pathway (see section 05 of this opinion).
- ▶ NALADOR (sulprostone) is a second-line uterotonic treatment of atonic postpartum haemorrhage resistant to first-line treatment with oxytocin (see section 08 of this opinion).

Public health impact

Considering:

- the seriousness of the postpartum haemorrhage and its prevalence,
 - the unmet medical need,
 - the lack of additional response to the identified need considering:
 - the absence of a demonstrated additional impact on morbidity and mortality,
 - the lack of any demonstrated impact on quality of life and the organisation of care,
- NALADOR (sulprostone) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of NALADOR (sulprostone) is substantial in the uterotonic treatment of atonic postpartum haemorrhage resistant to first-line treatment with oxytocin.

The Committee issues a favourable opinion for inclusion in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the uterotonic treatment of atonic postpartum haemorrhage resistant to first-line treatment with oxytocin and at the MA dosages.

Clinical Added Value

Considering:

- the recommended use of sulprostone, well established in clinical practice, in the uterotonic treatment of atonic postpartum haemorrhage resistant to first-line treatment with oxytocin,
- the availability of only descriptive efficacy and safety data in this indication,

the Transparency Committee considers that NALADOR (sulprostone) provides no clinical added value (CAV V) in the care pathway for atonic postpartum haemorrhage resistant to first-line treatment with oxytocin.