Summary Public Assessment Report

non-generics

Angusta
(Misoprostol)

DK/H/2584/001/DC

Date: 09-03-2017

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Angusta

Misoprostol, Tablet, 25 µg

This is a summary of the public assessment report (PAR) for Angusta. It explains how Angusta was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Angusta.

For practical information about using Angusta, patients should read the package leaflet or contact their doctor or pharmacist.

What is Angusta and what is it used for?

Angusta is used to help start the birth process.

How does Angusta work?

Misoprostol belongs to a group of medicines called prostaglandins. Prostaglandins have two actions during labour. One action is to soften the cervix so that the baby can be born through the vagina more easily. The second action is to cause contractions to start, which help push the baby out of the womb (uterus).

How is Angusta used?

The pharmaceutical form of Angusta is tablets and the route of administration is oral (taken by the mouth).

The recommended dose is 25 micrograms every two hours or 50 micrograms every four hours.
Angusta should be taken orally with a glass of water. The tablet should not be broken.
Your midwife or doctor will decide when administration of Angusta should stop.

Angusta will be given to you in the hospital.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Angusta have been shown in studies?

The applicant presented data from the scientific literature in addition to own data.
The literature provided and the studies conducted confirmed the efficacy and safety of misoprostol for induction of labour.

What are the possible side effects from Angusta?

The most common side effects with Angusta (which may affect more than 1 in 10 people) are:

- Nausea[1)]
- Vomiting [1)]
- Meconium stain (early faeces (stool) passed by the unborn baby into the amniotic fluid)
- Postpartum bleeding[2)] (loss of over 500 ml blood after delivery)

[1)] Reported as very common for Angusta 50 µg every 4 hours.
[2)] Reported as very common for Angusta 25 µg every 2 hours.

The common side effects with Angusta (which may affect up to 1 in 10 people) are:

- Apgar score low*[1)] (test performed at the baby at 1 and 5 minutes after birth, where the score of the test determines how well the baby is doing after being born)
- Foetal heart rate abnormal*[1)]
- Uterine hyperstimulation[2)] (uterine contractions are too strong, too frequent, or last too long)
- Diarrhoea
- Nausea[3)]
- Vomiting[3)]
- Postpartum bleeding[1)] (loss of over 500 ml blood after delivery)
- Chills

* Side effect in the baby
[1)] Reported as common for Angusta 50 µg every 4 hours.
[2)] Uterine hyperstimulation was reported both with and without foetal heart rate changes.
[3)] Reported as common for Angusta 25 µg every 2 hours.

For the full list of all side effects reported with Angusta, see section 4 of the package leaflet.

Angusta must not be used in patients:

- allergic to misoprostol or any of the other ingredients of this medicine (listed in section 6)
- if labour has started
- if the midwife or doctor consider the baby not to be in good health and/or is distressed
- if oxytocic medicines (medicines used to facilitate birth) and/or other medicines to help start the birth process are being given
- if previous surgery to the cervix (excluding conisation) or womb including a caesarean birth for any earlier babies has been made
- if any womb abnormality such as “heart-shaped” uterus (bicornuate uterus) that would prevent a vaginal delivery is present
- if the midwife or doctor judge that the placenta is covering the birth canal (placenta praevia) or if any unexplained vaginal bleeding after the 24th week of pregnancy has occured
- if the baby is in a position in the womb which prevents it from being born naturally (fetal malpresentation)
- with kidney failure (Glomerular filtration rate <15 ml/min/1.73 m^2

The additional safety concerns with Angusta are:

Summary of safety concerns	
Important identified risks	• Uterine hyperstimulation • Foetal heart rate disorder due to uterine hyperstimulation • Perinatal asphyxia due to uterine hyperstimulation • Uterine rupture
Important potential risks	• Unintentional overdose by patient
Missing information	• None

For the full list of restrictions, see the package leaflet.

Why is Angusta approved?

The member states involved in the procedure concluded that Angusta’s benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Angusta?

A risk management plan has been developed to ensure that Angusta is used as safely as possible. Based on this plan, safety information has been included in the summary of product

characteristics and the package leaflet for Angusta, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Angusta

The marketing authorisation for angusta was granted on March 1, 2017.

The full PAR and the package leaflet for Angusta can be found on the website http://mri.medagencies.org/Human/. For more information about treatment with Angusta, read the package leaflet or contact your doctor or midwife.

This summary was last updated in 03-2017.