PACKAGE LEAFLET

Package leaflet: Information for the user

ANGUSTA 25 micrograms tablets
misoprostol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your midwife, doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your midwife, doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Angusta is and what it is used for

Angusta contains the active substance misoprostol.
Angusta is used to help start the birth process.

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). There could be several reasons why you might need help to start this process. Ask your midwife or doctor if you want more information.

2. What you need to know before you take Angusta

Do not take Angusta:
- if you are allergic to misoprostol or any of the other ingredients of this medicine (listed in section 6)
- if labour has started
- if your midwife or doctor consider your 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 (see "Warnings and precautions", "Other medicines and Angusta" and "How to take Angusta" below).
- if you have had previous surgery to your cervix or womb including a caesarean birth for any earlier babies
- if you have any womb abnormality such as "heart-shaped" uterus (bicornuate uterus) that would prevent a vaginal delivery
- if your midwife or doctor judge that your placenta is covering the birth canal (placenta praevia) or if you have had any unexplained vaginal bleeding after the 24th week of pregnancy
- if your baby is in a position in the womb which prevents it from being born naturally (fetal malpresentation)
- if you have kidney failure (Glomerular filtration rate <15 ml/min/1.73 m^2

Warnings and precautions
Talk to your midwife, doctor or nurse before taking Angusta.

Angusta must only be given by a trained professional in a hospital where facilities for monitoring you and your baby are available. Your cervix will be assessed carefully before you take Angusta.

Angusta can cause excessive stimulation of the womb.

In case the womb contractions are prolonged or too strong or your doctor or nurse is concerned for you and your baby, you will not be given more tablets and your midwife or doctor will decide if you should be given medicines to reduce the strength or to slow down the frequency of your contractions.

The effect of Angusta has not been studied in women with severe pre-eclampsia (a condition where pregnant women suffer from high blood pressure, protein in the urine and possibly other complications).

Infections of the membranes surrounding the baby (chorioamnionitis) may necessitate fast delivery. The physician will take the necessary decisions regarding treatment with antibiotics, inducing labour or caesarean section.

There are no or limited experience with the use of Angusta in women whose membranes have been ruptured for more than 48 hours before the use of Angusta.

If your doctor finds that you need treatment with oxytocin (medicine used to facilitate birth), this will be carefully considered, as the treatment with oxytocin may affect the way Angusta works. It is recommended to wait 4 hours after the last dose of Angusta before giving oxytocin (see "Do not take Angusta" above, and "Other medicines and Angusta" and "How to take Angusta" below).

There is no experience with the use of Angusta to start the birth process in women who are pregnant with more than one baby and there is no experience with the use of Angusta in women who have had 5 or more previous babies delivered vaginally.

There is limited experience with the use of Angusta to start the birth process in women less than 37 weeks pregnant (see "Pregnancy, breast-feeding and fertility" below).

You should only take Angusta if your midwife or doctor judge that you have a medical need for help to start the birth process.

There is no or limited information with the use of Angusta in pregnant women with a Bishop Score >6 (Bishop Score is the most commonly used method to rate the readiness of the cervix).

An increased risk of formation of blood clots in the small blood vessels throughout the body (disseminated intravascular coagulation) after delivery has been described in patients whose labour has been induced by any method.

Dose adjustments may be needed in pregnant women with reduced kidney or liver function (see "How to take Angusta below).

Angusta contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Other medicines and Angusta
Tell your midwife or doctor if you are taking, have recently taken or might take any other medicines.

You must not take Angusta at the same time as other medicines used to facilitate birth and/or help start labour (see "Do not take Angusta"). It is recommended to wait 4 hours after the last dose of Angusta before giving oxytocin (see "Warnings and precautions" above, and "How to take Angusta" below).

Pregnancy, breast-feeding and fertility

Pregnancy

Angusta is used to help start labour from week 37 of pregnancy. When used at that time of pregnancy, there is no risk of birth defects for your baby. However, you should not use Angusta at any other time during pregnancy because misoprostol can then cause birth defects.

Breast-feeding

Misoprostol may be excreted in breast milk, but the level and duration is expected to be very limited and should not hinder breast-feeding. Breast-feeding can start 4 hours after the last dose of Angusta is given.

Fertility

There is no impact on fertility with the use of Angusta to help start labour from week 37 of the pregnancy.

3. How to take Angusta

Always take this medicine exactly as your midwife, doctor or nurse has told you. Check with your doctor if you are not sure. Angusta will be given to you by a trained professional in a hospital where facilities for monitoring you and your baby are available. Your cervix will be assessed carefully before you take Angusta.

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. Your midwife or doctor will stop administration of Angusta,

- if you have taken 200 micrograms over a period of 24 hours
- when labour starts
- if your contractions are too strong or last too long
- if your baby becomes distressed
- if treatment with oxytocin or other medicines used to facilitate birth is needed (see "Do not take Angusta", "Warnings and precautions" and "Other medicines and Angusta" above).

Use in patients with reduced kidney or liver function

Dose adjustments (lower dose and/or prolonged dosing intervals) may be needed in pregnant women with reduced kidney or liver function.

Use in children and adolescents

The use of Angusta has not been studied in pregnant women less than 18 years of age.

If you take more Angusta than you should

If you take more Angusta than you should, it may cause contractions to be too strong or last too long or the baby may become distressed. Administration of Angusta must then be stopped. Your midwife or doctor will decide if you should be given medicines to reduce the strength or to slow down the frequency of your contractions or if the baby should be delivered by caesarean section.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may occur when using Angusta.

Very Common: may affect more than 1 in 10 people

- 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 micrograms every 4 hours.
[2)] Reported as very common for Angusta 25 micrograms every 2 hours.

Common: may affect up to 1 in 10 people
- 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
- Elevation of body temperature

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

Uncommon: may affect up to 1 in 100 people
- 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)]

* Side effect in the baby
[1)] Reported as uncommon for Angusta 25 micrograms every 2 hours.

Not known: Frequency cannot be estimated from the available data
- Dizziness
- Convulsion neonatal* (seizures in the newborn baby)
- Neonatal asphyxia* (lack of oxygen to the baby's brain and organs during the birth)
- Cyanosis neonatal* (also called "blue baby syndrome" characterised by blue coloration of the skin and mucous membranes in the newborn baby)
- Rash pruritic (itchy rash)
- Foetal acidosis* (high acid level in the unborn baby's blood)
- Premature separation of placenta (separation of the placenta from the wall of the uterus before birth)
- Uterine (uterus) rupture

* Side effect in the baby

Reporting of side effects
If you get any side effects, talk to your midwife, doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

IE: HPRA Pharmacovigilance Website: www.hpra.ie.
MT: http://www.medicinesauthority.gov.mt/adrportal.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Angusta

Keep this medicine out of the sight and reach of children.

Store in the original package in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the foil and carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater. Ask your midwife, doctor or pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Angusta contains

- The active substance is misoprostol. Each tablet contains 25 micrograms of misoprostol.
- The other ingredients are: hypromellose; cellulose, microcrystalline; maize starch; crospovidone; croscarmellose sodium; silica, colloidal anhydrous.

What Angusta looks like and contents of the pack

Angusta is a white, uncoated oval shaped tablet with the dimensions 7.5 x 4.5 mm with a score line on one side and plain on the other. The score line is not intended for breaking the tablet.

Angusta tablets are packaged in blister packs supplied in a cardboard box containing 8 tablets.

Marketing Authorisation Holder

Norgine B.V.
Antonio Vivaldistraat 150
1083HP Amsterdam
The Netherlands

Manufacturer(s)

Norgine B.V.
Antonio Vivaldistraat 150
1083HP Amsterdam
The Netherlands

This medicinal product is authorised in the Member States of EEA under the following name:

Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and United Kingdom (Northern Ireland): ANGUSTA

This leaflet was last revised in 10/2023.

Other sources of information

If you need the information on this leaflet in an alternative format, such as large text, please ring Medical Information on +44 (0) 1895 826 606.