PACKAGE LEAFLET

Package leaflet: Information for the user

<Product name> 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 <Product name> is and what it is used for

<Product name> contains the active substance misoprostol.
<Product name> 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 <Product name>

Do not take <Product name>:
- 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 <Product name>" and "How to take <Product name>" below).
- if you have had previous surgery to your cervix (excluding conisation) 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 <Product name>.

<Product name> 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 <Product name>.

<Product name> 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 <Product name> 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 <Product name> in women whose membranes have been ruptured for more than 48 hours before the use of <Product name>.

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 <Product name> works. It is recommended to wait 4 hours after the last dose of <Product name> before giving oxytocin (see "Do not take <Product name>" above, and "Other medicines and <Product name>" and "How to take <Product name>" below).

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

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

You should only take <Product name> 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 <Product name> 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 <Product name> below).

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

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

Pregnancy, breast-feeding and fertility

Pregnancy
[Product] 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 [product] 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 <Product name> is given.

Fertility
There is no impact on fertility with the use of <Product name> to help start labour from week 37 of the pregnancy.

3. How to take <Product name>

Always take this medicine exactly as your midwife, doctor or nurse has told you. Check with your doctor if you are not sure. <Product name> 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 <Product name>.

The recommended dose is 25 micrograms every two hours or 50 micrograms every four hours. <Product name> should be taken orally with a glass of water. The tablet should not be broken.
Your midwife or doctor will decide when administration of <Product name> should stop. Your midwife or doctor will stop administration of <Product name>,
- 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 <Product name>", "Warnings and precautions" and "Other medicines and <Product name>" 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 <Product name> has not been studied in pregnant women less than 18 years of age.

If you take more <Product name> than you should
If you take more <Product name> than you should, it may cause contractions to be too strong or last too long or the baby may become distressed. Administration of <Product name> 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 <Product name>.

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 <Product name> 50 µg every 4 hours.

[2)] Reported as very common for <Product name> 25 µg 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 <Product name> 50 µg every 4 hours.
[2)] Uterine hyperstimulation was reported both with and without foetal heart rate changes.
[3)] Reported as common for <Product name> 25 µg every 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 <Product name> 25 µg 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 the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store <Product name>

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 <Product name> contains
- The active substance is misoprostol.
- The other ingredients are: hypromellose; cellulose, microcrystalline; maize starch; crospovidone; croscarmellose sodium; silica, colloidal anhydrous.

What <Product name> looks like and contents of the pack
<Product name> 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.

<Product name> tablets are packaged in blister packs supplied in a cardboard box containing 8 tablets.

Marketing Authorisation Holder

Azanta Danmark A/S
Gearhalsvej 1
2500 Valby
Denmark

Manufacturer

Piramal Healthcare (UK) Limited
Whalton Road,
Morpeth,
Northumberland,
NE61 3YA, UK

Azanta Danmark A/S
Gearhalsvej 1
2500 Valby
Denmark

This medicinal product is authorised in the Member States of EEA under the following names:
Bulgaria: Ангуста 25 микрограма таблетки
Croatia: Angusta 25 mikrograma tablete
Czech Republic: Angusta 25 mikrogramů tablety
Denmark: Angusta
Estonia: Angusta
Finland: Angusta 25 mikrog tabletit
France: Angusta 25 microgrammes, comprimé
Hungary: Angusta 25 mikrogramm tabletta
Iceland: Angusta 25 míkróg töflur
Latvia: Angusta 25 mikrogrami tabletes
Norway: Angusta
Poland: Angusta
Romania: Angusta 25 micrograme comprimate
Slovakia: Angusta 25 mikrogramov tablety
Slovenia Angusta 25 mikrogramov tablete
Sweden: Angusta

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