

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor, midwife, or pharmacist.

### 1. Why am I being given ANGUSTA?

ANGUSTA contains the active ingredient misoprostol. ANGUSTA is used to help start the birth process.

For more information, see Section [1. Why am I being given ANGUSTA?](#) in the full CMI.

### 2. What should I know before being given ANGUSTA?

Do not use if you have ever had an allergic reaction to ANGUSTA or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions or take any other medicines. ANGUSTA must only be given by a trained professional in a hospital where facilities for monitoring you and your baby are available.**

For more information, see Section [2. What should I know before being given ANGUSTA?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with ANGUSTA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How will I be given ANGUSTA?

- ANGUSTA should be taken orally with a glass of water. The tablet should not be broken.

More instructions can be found in Section [4. How will I be given ANGUSTA?](#) in the full CMI.

### 5. What should I know while being given ANGUSTA?

Things you should do	<ul style="list-style-type: none"><li>• 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.</li></ul>
Driving or using machines	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how ANGUSTA affects you.</li></ul>
Drinking alcohol	<ul style="list-style-type: none"><li>• There is no information on the use of alcohol with ANGUSTA.</li></ul>
Looking after your medicine	<ul style="list-style-type: none"><li>• ANGUSTA will be kept in a cool dry place where the temperature stays below 25°C.</li></ul>

For more information, see Section [5. What should I know while being given ANGUSTA?](#) in the full CMI.

### 6. Are there any side effects?

Side effects that are common and less serious include dizziness, nausea, vomiting, meconium stain (early faeces (stool) passed by the unborn baby into the amniotic fluid, chill, fever.

Serious side effects which can affect neonates and need immediate medical attention include foetal heart rate abnormal, seizures in new born baby, lack of oxygen to the baby's brain and organs during the birth, blue coloration of the skin and mucous membranes in the new-born baby.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

### Consumer Medicine Information (CMI)

This leaflet provides important information about using ANGUSTA. **You should also speak to your doctor, midwife or nurse if you would like further information or if you have any concerns or questions about using ANGUSTA.**

#### Where to find information in this leaflet:

- [1. Why am I being given ANGUSTA?](#)
- [2. What should I know before being given ANGUSTA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given ANGUSTA?](#)
- [5. What should I know while being given ANGUSTA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I being given ANGUSTA?

**ANGUSTA contains the active ingredient 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 should I know before being given ANGUSTA?

#### Warnings

##### Do not use ANGUSTA if:

- you are allergic to misoprostol, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- labour has started
- your midwife or doctor consider your baby not to be in good health and/or is distressed
- oxytocic medicines (medicines used to facilitate birth) and/or other medicines to help start the birth process are being given
- you have had previous surgery to your cervix or womb including a caesarean birth for any earlier babies
- you have any womb abnormality such as “heart-shaped” uterus (bicornuate uterus) that would prevent a vaginal delivery

- 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
- your baby is in a position in the womb which prevents it from being born naturally (foetal malpresentation)
- you have kidney failure.

#### Check with your doctor if you:

- have severe pre-eclampsia (a condition where pregnant women suffer from high blood pressure, protein in the urine and possibly other complications).
- have reduced kidney or liver function.
- have infections of the membranes surrounding the baby (chorioamnionitis). This may necessitate fast delivery. The physician will take the necessary decisions regarding treatment with antibiotics, inducing labour or caesarean section.

#### You should know the following before taking ANGUSTA

- ANGUSTA can cause excessive stimulation of the womb.
- 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.
- 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.
- 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 limited experience with the use of ANGUSTA to start the birth process in women less than 37 weeks pregnant.
- 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.

Check with your doctor if you take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## 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.

## Breastfeeding

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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 immediately after birth.

## Use in children

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

## 3. What if I am taking other medicines?

Tell your doctor or midwife if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

### Some medicines may interfere with ANGUSTA and affect how it works

You must not take ANGUSTA at the same time as other medicines used to facilitate birth and/or help start labour. It is recommended to delay 4 hours after the last dose of ANGUSTA before oxytocin is given.

**Check with your doctor, nurse or midwife if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ANGUSTA.**

## 4. How will I be given ANGUSTA?

### How much to take

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.

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.

## How to take ANGUSTA

- ANGUSTA should be taken orally with a glass of water. The tablet should not be broken.

## 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.

## If you use too much ANGUSTA

If you think that you have been given too much ANGUSTA, you may need urgent medical attention.

### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor

If you have been given 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.

## 5. What should I know while being given ANGUSTA?

### Things you should do

- 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.
- 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.

### Driving or using machines

Be careful before you drive or use any machines or tools until you know how ANGUSTA affects you.

### Drinking alcohol

There is no information on the use of alcohol with ANGUSTA.

### Looking after your medicine

- ANGUSTA will be kept in a cool dry place where the temperature stays below 25°C.
- Heat or moisture may cause ANGUSTA tablets to deteriorate.

**It will be kept where young children cannot reach it.**

## When to discard your medicine

Keep your tablets in their blister until it is time to take them. If you take the tablets out of the blister they may not keep well.

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, midwife or nurse if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<b>Brain and nerves:</b> <ul style="list-style-type: none"><li>dizziness</li></ul> <b>Gut and digestion:</b> <ul style="list-style-type: none"><li>nausea</li><li>vomiting</li></ul> <b>Skin and nails:</b> <ul style="list-style-type: none"><li>rash</li></ul> <b>Body as a whole:</b> <ul style="list-style-type: none"><li>chills</li><li>fever</li></ul> <b>Pregnancy and birth related</b> <ul style="list-style-type: none"><li>meconium stain (early faeces (stool) passed by the unborn baby into the amniotic fluid)</li><li>postpartum bleeding (loss of over 500 ml blood after delivery)</li><li>uterine contractions are too strong, too frequent, or last too long (uterine hyperstimulation)</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

### Serious side effects

Serious side effects	What to do
<b>Brain and nerves:</b> <ul style="list-style-type: none"><li>seizures in the new-born baby*</li></ul> <b>Lungs and upper airways</b> <ul style="list-style-type: none"><li>seizures in the new-born baby* (convulsion neonatal)</li><li>lack of oxygen to the baby's brain and organs during the birth* (Neonatal asphyxia)</li></ul>	<b>Speak to your doctor immediately if you experience any of these serious side effects.</b>

### Pregnancy and birth related

- uterine contractions are too strong, too frequent, or last too long (uterine hyperstimulation)
- separation of the placenta from the wall of the uterus before birth (premature separation of placenta)
- uterine (uterus) rupture
- high acid level in the unborn baby's blood\* (foetal acidosis)
- Apgar score low\* (test performed on 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\*

\*side effects in baby

**Tell your doctor, midwife or nurse if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What ANGUSTA contains

<b>Active ingredient (main ingredient)</b>	Misoprostol
<b>Other ingredients (inactive ingredients)</b>	Hypromellose, microcrystalline cellulose, maize starch, crospovidone, croscarmellose sodium, colloidal anhydrous silica.

**Do not take this medicine if you are allergic to any of these ingredients.**

### What ANGUSTA looks like

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.

AUST R 381571

## **Who distributes ANGUSTA**

Norgine Pty Ltd  
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Frenchs Forest NSW 2086  
Australia  
Website: [www.norgine.com.au](http://www.norgine.com.au)

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This leaflet was prepared in October 2022.