SYNTOCINON®

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I given SYNTOCINON?

SYNTOCINON contains the active ingredient synthetic oxytocin. SYNTOCINON is used to bring on (induce) labour. It can also be used during and immediately after delivery to help the birth and to prevent or treat excessive bleeding.

For more information, see Section <u>1. Why am I using SYNTOCINON?</u> in the full CMI.

2. What should I know before I am given SYNTOCINON?

Do not use if you have ever had an allergic reaction to SYNTOCINON 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.

For more information, see Section 2. What should I know before I use SYNTOCINON? in the full CMI.

3. What if I am taking other medicines?

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

For more information, see Section 3. What if I am taking other medicines? in the full CMI.

4. How is SYNTOCINON given?

 SYNTOCINON must only be given by a doctor or nurse.

More instructions can be found in Section <u>4. How do I use SYNTOCINON?</u> in the full CMI.

5. Are there any side effects?

Tell your doctor or nurse immediately if you notice any of the following symptoms:

Rash, itching or hives on the skin, swelling of the face, lips, tongue, throat, or other parts of the body, shortness of breath, wheezing or troubled breathing, headache, nausea (feeling sick) or vomiting, feeling drowsy and lethargic, pain in the abdomen that is different from labour pains, dizziness, light headedness or faintness, flushing of the face, chest pain, fast, slow or irregular heartbeat, excessive or continuous contractions, abnormal clotting or bleeding.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

SYNTOCINON®

Active ingredient(s): synthetic oxytocin

Consumer Medicine Information (CMI)

This leaflet provides important information about using SYNTOCINON. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using SYNTOCINON.

Where to find information in this leaflet:

- 1. Why am I given SYNTOCINON?
- 2. What should I know before I am given SYNTOCINON?
- 3. What if I am taking other medicines?
- 4. How is SYNTOCINON given?
- 5. Are there any side effects?
- 6. Product details

1. Why am I using SYNTOCINON?

SYNTOCINON contains the active ingredient synthetic oxytocin. SYNTOCINON is a man-made chemical that is identical to a natural hormone called oxytocin. It works by stimulating the muscles of the uterus (womb) to produce rhythmic contractions.

SYNTOCINON is used to bring on (induce) labour. It can also be used during and immediately after delivery to help the birth and to prevent or treat excessive bleeding.

SYNTOCINON is not suitable in all situations - for example, if the baby or placenta are in the wrong position or if you have had a previous caesarean section or other surgery involving the uterus. Your doctor can give you more information on the suitability of SYNTOCINON in your particular case.

Ask your doctor if you have any questions about why SYNTOCINON has been prescribed for you.

Your doctor may have prescribed it for another purpose.

SYNTOCINON is only available with a doctor's prescription. It is not addictive.

2. What should I know before I use SYNTOCINON?

Warnings

You must not have SYNTOCINON if:

- you are allergic to oxytocin (the active ingredient), latex or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may include:
 - shortness of breath
 - wheezing or difficulty breathing
 - swelling of the face, lips, tongue or other parts of the body
 - rash, itching or hives on the skin.

Always check the ingredients to make sure you can use this medicine.

- your doctor thinks that inducing or enhancing contractions for normal labour and vaginal delivery would be unsuitable for you or your baby
- there are maternal or foetal reasons for caesarean delivery
- you have been given medicines called prostaglandins within the past 6 hours

Check with your doctor if you:

 have high blood pressure or any heart or kidney problems. Your doctor may want to take extra precautions. For example, the amount of fluid you will be given may need to be reduced if you have a problem with your heart or kidneys.

 are allergic to any other medicines, foods, dyes or preservatives.

Your doctor will want to know if you are prone to allergies.

- have, or have ever had, any of the following problems:
 - an abnormal electrical signal called "prolongation of the QT interval"
 - any other conditions that affect the heart
 - kidney problems
- are taking any medicines that may affect your heart, or any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.
- have been given anaesthetics or medicines called prostaglandins.

If you have not told your doctor about any of these things, tell him/her before you have SYNTOCINON.

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 <u>6</u>. Are there any side effects?

3. What if I am taking other medicines?

Tell your doctor or pharmacist 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.

4. How SYNTOCINON is given?

To bring on (induce) or maintain labour, SYNTOCINON is given by intravenous infusion (drip). The speed of the infusion is set to maintain a pattern of contractions similar to normal labour. During the infusion, both you and your baby will be closely monitored to prevent complications.

If SYNTOCINON is needed at delivery or to prevent excessive bleeding, it can also be given intramuscularly (into a muscle) or by slow intravenous injection directly into a vein.

5. Are there any side effects?

Tell your doctor or nurse as soon as possible if you do not feel well while you are having SYNTOCINON.

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 or nurse if you have any further questions about side effects.

Side effects

| Side effects | What to do |
|--|--|
| rash, itching or hives on the skin swelling of the face, lips, tongue, throat, or other parts of the body (possible signs of a reaction called angioedema) shortness of breath, wheezing or troubled breathing headache nausea (feeling sick) or vomiting feeling drowsy and lethargic pain in the abdomen that is different from labour pains dizziness, light headedness or faintness flushing of the face chest pain | Tell your doctor or nurse immediately if you notice any of the following symptoms: |

| Side effects | What to do |
|---|------------|
| fast, slow or irregular heartbeat | |
| excessive or continuous contractions | |
| abnormal clotting or bleeding | |
| low level of salt in the blood (shown in a blood test) | |
| The above symptoms may be signs of allergy or signs of too much fluid associated with high doses or long infusions. | |

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

6. Product details

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

What SYNTOCINON contains

| Active ingredient (main ingredient) | Each ampoule contains 5 or 10 International Units (IU) of oxytocin. |
|--|--|
| Other ingredients (inactive ingredients) | sodium acetate trihydrate glacial acetic acid chlorobutanol hemihydrate ethanol water for injections |
| Potential allergens | N/A |

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

What SYNTOCINON looks like

SYNTOCINON 5 IU or 10 IU is available in a glass ampoule containing 1 mL of a clear, colourless solution; 5 ampoules in a cardboard carton. (AUST R 13395; 13383)

Who distributes SYNTOCINON

Viatris Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

SYNTOCINON® is a Viatris company trade mark

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