

Oxytocin APX Solution for Injection

Oxytocin

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about oxytocin. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What this medicine is used for

Oxytocin can be 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.

Oxytocin 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 whether oxytocin is suitable for you.

How it works

Oxytocin 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.

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

Your doctor may have prescribed this medicine for another reason.

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

This medicine is not addictive.

This medicine should not be used in children.

Before are given this medicine

When you must not be given this medicine

Do not receive this medicine if you have an allergy to:

- oxytocin
- latex
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body

- rash, itching or hives on the skin

You should not receive this medicine if:

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

Do not receive this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you are given this medicine

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have ever had any of the following medical conditions:

- high blood pressure
- abnormal heart electrical signals (QT interval prolongation)
- any other heart conditions
- kidney problems

If you have not told your doctor about any of the above, tell them

before you start taking this medicine.

Taking other medicines

Tell your doctor and pharmacist that you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interact with oxytocin. These include:

- prostaglandins and their analogues, used to help bring on contractions
- inhalation or caudal anaesthetics
- medicines affecting your heart
- medicines that prolong the QT interval
- vasoconstrictors/sympathomimetics, which can act on blood vessels

These medicines may be affected by this medicine or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to this medicine is given

How much is given

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your age and other medicines that are being given.

How it is given

To bring on (induce) or maintain labour, oxytocin 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 oxytocin 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.

If you receive too much (overdose)

As oxytocin is given to you in a hospital under the supervision of your doctor or medical staff, it is very unlikely that you will receive an overdose. You will be closely monitored while in the hospital so that any unwanted side effects can be treated. However, if you experience severe side effects tell your doctor and nurse immediately.

Side effects

Tell your doctor and nurse as soon as possible if you do not feel well while you are receiving oxytocin.

This medicine helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- 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 heart beat
- excessive or continuous contractions
- abnormal clotting or bleeding
- shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin (signs of a severe allergic reaction)

The above list includes some symptoms that may require urgent medical attention.

Tell your doctor and nurse if you notice anything else that is making you feel unwell.

Other side effects not listed above may happen in some people.

Storage and Disposal

Storage

This medicine will be stored in the pharmacy or on the ward. It is stored at 2-8°C (do not freeze).

Protect from light. Do not freeze.

Disposal

Oxytocin is used for one dose in one patient only. Any remaining contents should be discarded.

Product description

What it looks like

Clear and colourless sterile aqueous solution, with a characteristic odour. Available in ampoules containing 10 IU in 1 mL.

Ingredients

Each ampoule contains 10 IU of synthetic oxytocin as the active ingredient.

It also contains the following:

- glacial acetic acid
- chlorobutanol hemihydrate

- water for injections

This medicine does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Australian Registration Numbers

Oxytocin APX 10 IU in 1 mL glass ampoules: AUST R 225656.

Sponsor

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