

Oxytocin APOTEX Solution for Injection

Contains the active ingredient synthetic oxytocin

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before taking your medicine.

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

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

This leaflet should be kept with your medicine, in case you may want to read it again.

What this medicine is used for

The name of your medicine is Oxytocin APOTEX Solution for Injection. It contains the active ingredient synthetic oxytocin.

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 the suitability of oxytocin in your particular case.

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.

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.

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children.

Before you are given this medicine

When you must not be given this medicine

This medicine should not be given 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.
- **You are hypersensitive to, or have had an allergic reaction to, oxytocin or any of the ingredients listed at the end of this leaflet.** Symptoms of an allergic reaction may include: cough, 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; fainting; or hay fever-like symptoms. **If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.**
- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you are given the medicine

Tell 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.

Tell your doctor if you have, or have ever had, any of the following problems:

- an abnormal heart electrical signal called "prolongation of the QT interval"
- any other conditions that affect the heart
- kidney problems.

Before you are given this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You are planning to have surgery or an anaesthetic.
3. You are currently receiving or are planning to receive dental treatment.
4. You are taking or are planning to take any other medicines that may affect your heart, or any other medicines, including medicines that you buy without a prescription. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with oxytocin. These include:

- Prostaglandins and their analogues (which also facilitate contraction)
- Inhalation anaesthetics
- Caudal anaesthetics
- Drugs prolonging QT interval
- Vasoconstrictors/ Sympathomimetics (which can act on blood vessels).

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with oxytocin.

How 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 contact your medical or nursing staff immediately.

Your doctor has information on how to recognise and treat an overdose. Ask your doctor or healthcare professional if you have any concerns.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking oxytocin or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor 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

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 is making you feel unwell.

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

Allergic reactions

If you think you are having an allergic reaction to Oxytocin, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, 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
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

This medicine will be stored in the pharmacy or on the ward. It is kept in a cool dry place where the temperature stays below 25°C.

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 Oxytocin APOTEX Solution for Injection looks like

Oxytocin injection is a sterile aqueous solution containing synthetic oxytocin. The solution is clear and colourless.

Oxytocin is available in ampoules containing, 5 IU in 1 mL and 10 IU in 1 mL.

Ingredients

Each ampoule contains 5 IU or 10 IU as the active ingredient.

It also contains the following inactive ingredients:

- glacial acetic acid
- chlorbutol
- water for injections

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

Oxytocin APOTEX 5 IU in 1mL glass ampoules: AUST R 225657.

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

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

APO and APOTEX are registered trade marks of Apotex Inc.

This leaflet was last updated in:
October 2017