

Oxytocin Sandoz®

synthetic oxytocin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Oxytocin Sandoz.

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 having Oxytocin Sandoz against the benefits they expect it to provide.

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

Keep this leaflet.

You may need to read it again.

What Oxytocin Sandoz is used for

Oxytocin Sandoz 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 Sandoz 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.

Oxytocin Sandoz 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 Caesarian section or other surgery involving the uterus. Your doctor can give you more information on the suitability of

Oxytocin Sandoz in your particular case.

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

Your doctor may have prescribed it for another purpose.

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

Before you have Oxytocin Sandoz

When you must not have it

You must not have Oxytocin Sandoz if:

- 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
- you are allergic to oxytocin (the active ingredient) or any of the other 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.

Before you have it

Tell your doctor if you have high blood pressure, 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 are allergic to any other medicines, foods, dyes or preservatives.

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

Tell your doctor if you 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.

Tell your doctor if you 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.

Tell your doctor if you 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 Oxytocin Sandoz.

How Oxytocin Sandoz is given

To bring on (induce) or maintain labour, Oxytocin Sandoz 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 Sandoz 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.

Side effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the 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 (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
- fast, slow or irregular heart beat
- 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 is making you feel unwell.

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

Product description

What it looks like

Oxytocin Sandoz 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.

Ingredients

Each ampoule contains either 5 or 10 International Units (IU) of oxytocin.

It also contains:

- sodium acetate
- glacial acetic acid
- chlorbutol
- ethanol 94%
- water for injections.

Supplier

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park NSW 2113
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