OXYTOCIN GH

(oxytocin) solution for injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Oxytocin GH.

It does not contain all the available information. It does not take the place of talking with your doctor or pharmacist.

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

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of your treatment using Oxytocin GH against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again

What Oxytocin GH is used for

Oxytocin GH 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 GH 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 GH 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 GH in your particular case.

Ask your doctor if you have any questions about why Oxytocin GH has been prescribed for you. Your doctor may have prescribed it for another purpose.

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

Before you are given Oxytocin GH

When you must not use it

You must not have Oxytocin GH 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.

• You are allergic to latex. 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 are given it

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 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;
- liver 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 GH.

How Oxytocin GH is given

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

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 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 is making you feel unwell.

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

After using Oxytocin GH

Storage

Store unopened Oxytocin GH ampoules in a refrigerator, where the temperature stays between 2°C to 8°C. Protect from light and do not freeze.

The unopened product may be stored for up to three (3) months at or below 25°C. Once removed from the refrigerator the product must be discarded if not used. It must not be returned to the refrigerator.

Oxytocin GH will be kept in a locked cupboard in the hospital pharmacy or operating theatre.

Oxytocin GH should not be used after the date (month and year) printed after "EXP". The anaesthetist will inspect Oxytocin GH before use to determine that it is still within its use by date.

Disposal

The hospital staff looking after you will dispose of any remaining Oxytocin GH appropriately.

Product description

What it looks like

Oxytocin GH is a clear, colourless solution.

A carton of Oxytocin GH contains 1, 5 or 10 ampoules.

Not all pack sizes may be marketed.

Ingredients

Active ingredient

Oxytocin GH is available in 1 mL glass ampoules containing either 8.3 microgram (5 IU) or 16.7 micrograms (10 IU) of oxytocin.

Other ingredients

- glacial acetic acid;
- sodium acetate;
- sodium chloride;
- water for injections.

Australian Registration Numbers

Oxytocin GH 5 IU/1 mL: AUST R 207985

Oxytocin GH 10 IU/1 mL: AUST R 207986

Sponsor

Generic Health Pty Ltd Suite 2, Level 2 19-23 Prospect Street Box Hill, VIC, 3128 Australia

E-mail: ghinfo@generichealth.com.au Telephone: +61 3 9809 7900 Website: www.generichealth.com.au

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