INFORMATION FOR THE USER

Cervagem Pessary 1mg gemeprost

Is this leaflet hard to see or read? Phone 0845 372 7101 for help

Read all of this leaflet carefully before you use Cervagem Pessary

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If any of the effects gets worse, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

In this leaflet:

1. What Cervagem Pessary is and what it is used for
2. What you need to know before you use Cervagem Pessary
3. How you are given Cervagem Pessary
4. Possible side effects
5. How Cervagem Pessary is stored
6. Contents of the pack and other information

1. What Cervagem Pessary is and what it is used for

Cervagem Pessary contains a prostaglandin E1 (gemeprost) pessary. It works by making the womb contract. Cervagem Pessary is normally given to women in the following situations:

- To terminate a pregnancy in the first three months of pregnancy.
- To terminate a pregnancy between the fourth and sixth month.
- To terminate a pregnancy between the fifth and sixth month, if the womb has already begun to thin.

2. What you need to know before you use Cervagem Pessary

You are allergic (hypersensitive) to prostaglandins or other medicines such as oxytocin. This can increase the effect of Cervagem. Do not use Cervagem pessaries if any of the following apply to you. If you are not sure, talk to your doctor or nurse before you are given this medicine:

- You have had an operation on your womb, like a caesarean section.
- You have breathing problems.
- You have had an allergy reaction in the eye which affects your sight.
- You have any heart problems.
- You have diabetes mellitus.
- You have any rare genetic disease known as sickle cell anaemia.
- You have epilepsy.
- You have unusual vaginal discharge, pain when passing water or increased need to pass water.
- You have breathing problems.
- You have unusual vaginal discharge.
- You have vaginal pain, itching or swelling.
- You have unusual vaginal discharge.

3. How you are given Cervagem Pessary

One pessary to be inserted into the posterior vaginal fornix at 3-hourly intervals to a maximum of 5 administrations. If abortion is not well established after 5 pessaries, a second course of treatment may be initiated starting 12 hours after the initial commencement of treatment. If abortion is not well established after 10 pessaries, a further course of CERVAGEM treatment is not recommended and alternative treatment should be employed to effect uterine evacuation.

4. Possible side effects

In particular, tell your doctor or nurse if you are taking or have recently taken any other medicines, including medicines obtained without prescription. This includes medicines you can buy without prescription, including herbal medicines. This is because Cervagem can affect the way some medicines work. Also some medicines can affect the way Cervagem works. In particular, tell your doctor or nurse if you are taking any of the following medicines.

Medicines used to speed up labour such as oxytocin. This can increase the effect of Cervagem.

5. How will you be given Cervagem Pessary

Cervagem pessaries will be given to you by a doctor or nurse.

The pessaries are inserted into your vagina.

The number of pessaries given to you will depend on the reason for its use. The doctor or nurse may decide to stop the treatment if:

- You have breathing problems.
- You have unusual vaginal discharge.
- You have vaginal pain, itching or swelling.
- You have unusual vaginal discharge.

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6. Contents of the pack and other information

This leaflet is written for patients in the second trimester of gestation. In licensed indications, induction of abortion of pregnancy in patients in the second trimester of gestation, is licensed indications.

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Termination of pregnancy in the first three months to make the operation easier
• One pessary inserted three hours before the operation
• If the operation is delayed for more than 1 hour, you will be kept under observation. This is because terminal cervical dilatation may occur.
• If you start to bleed, tell the doctor or nurse.
Termination of pregnancy between the fourth and sixth month
• One pessary inserted every three hours
• Up to 5 pessaries are normally given.
• If the termination has not happened by this time, your doctor or nurse will use another method to finish the termination.
Termination of a pregnancy between the fourth and sixth month, if the unborn child (foetus) has already died
• One pessary will be inserted every three hours.
• Up to 5 pessaries are normally given.
After the treatment, the doctor or nurse will check to make sure the termination has been completed.
It is important to keep your appointment if you are having a follow-up examination after this treatment.

4. Possible side effects

Like all medicines, Cervagem Pessary can cause side effects, although not everybody gets them.
Very rare allergic reactions that can occur with prostaglandins such as Cervagem
You could notice the following signs of an allergic reaction:
• Shuffling, fascinating, face and limbs and all over your body
• Tightness and difficulty in breathing
If you think that Cervagem is causing an allergic reaction, tell your doctor straight away.
Very rare side effects

• Spirituality or tearing of the womb. This is usually in patients who have had several children or a previous operation. It is a rare occurrence in such cases (a similar reaction)
• Heart and circulation problems

If you have any of the following side effects, do not worry. However, if they are troublesome, talk to your doctor or nurse.
These side effects usually last for a short time
• Breeding from your vagina and mild pain and cramps (long period pain)
• Feeling sick (nausea) and being sick

If you get any of the following side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

5. How to store

Cervagem Pessary

• Keep this medicine in a safe place where children cannot see or reach it.
• Store below minus 10°C (-10°C) in a freezer.
• Do not use Cervagem Pessary after the expiry date stated on the box and the foil pouches. The expiry date refers to the last day of that month
• Before use, each pessary should be allowed to warm up to room temperature.

6. Contents of the pack and other information

What Cervagem Pessary contains
• The active substance is gamprogyn.
• The other ingredients are: gelatin 5 52 and dehydrated ethanol.

What Cervagem Pessary looks like and are the presentations of the medicine
The pessary is a bi-elliptical shaped waxy solid, 2.3 centimetres long and it comes in boxes of 5 pessaries.

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.
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Cervagem Pessary

Pirfenidone, dexamethasone, teniposide, vincristine, cisplatin, cyclophosphamide, dacarbazine, doxorubicin, ifosfamide, mitomycin, methotrexate, cyclosporine, immunomodulators, cytotoxic agents in the central nervous system (CNS) and relax the smooth muscle, leading to hypotension, chest pain, nausea and vomiting.
A somnolent or apathetic patient with a poor airway should be in view of impending toxicity is likely to be sedation, vomiting, confusion, unconsciousness, abnormal pain and diarrhoea, which may be bloody, palpitations or bradycardia, febrile, vomiting, confusion, abnormal pain and diarrhoea.
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