CERVAGEM®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using CERVAGEM?

CERVAGEM contains the active ingredient gemeprost. CERVAGEM is used for the dilation and softening of the cervix prior to surgical procedures during pregnancy or for the induction of miscarriage.

For more information, see Section 1. Why am I using CERVAGEM? in the full CMI.

2. What should I know before I use CERVAGEM?

Do not use if you have ever had an allergic reaction to CERVAGEM or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use CERVAGEM? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CERVAGEM and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use CERVAGEM?

CERVAGEM is administered by insertion via the vagina by a doctor or nurse.

More instructions can be found in Section 4. How do I use CERVAGEM? in the full CMI.

5. What should I know while using CERVAGEM?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you have been administered CERVAGEM.
Things you should not do	• Do not use CERVAGEM if you are allergic to gemeprost, or any of the ingredients listed at the end of this leaflet • Do not use if your pregnancy is near full term, or you have previously experienced a difficult labour or delivery.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how CERVAGEM affects you
Drinking alcohol	• Tell your doctor if you drink alcohol.
Looking after your medicine	• Store below -10°C (freeze) in the original pack.

For more information, see Section 5. What should I know while using CERVAGEM? in the full CMI.

6. Are there any side effects?

Common side effects: vaginal bleeding or uterine pain, nausea, vomiting, lower abdominal pain, backache, headache, slight fever, flushing, chills, dizziness, lightheadedness, irregular heartbeats, muscle weakness, shortness of breath.

Tell your doctor or nurse immediately if you notice any of the following: asthma, wheezing or shortness of breath, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, hives, itching, skin rash or fainting. These are symptoms of an allergic reaction. Serious side effects may also include: fainting, chest spasm or pain, prolonged or spasmotic pelvic/lower back pain. You may need urgent medical attention. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

CERVAGEM®

Active ingredient(s): *gemeprost*

Consumer Medicine Information (CMI)

This leaflet provides important information about using CERVAGEM. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using CERVAGEM.**

Where to find information in this leaflet:

1. Why am I using CERVAGEM?
2. What should I know before I use CERVAGEM?
3. What if I am taking other medicines?
4. How do I use CERVAGEM?
5. What should I know while using CERVAGEM?
6. Are there any side effects?
7. Product details

1. Why am I using CERVAGEM?

CERVAGEM contains the active ingredient gemeprost. Gemeprost is a member of the prostaglandin class of medicines. Prostaglandins are hormone-like substances which stimulate changes to the uterus and cervix.

CERVAGEM is used for the dilation and softening of the cervix prior to surgical procedures during pregnancy or for the induction of miscarriage.

Your doctor may have prescribed Cervagem for another reason.

2. What should I know before I use CERVAGEM?

Warnings

Do not use CERVAGEM if:

- you are allergic to gemeprost, or any of the ingredients listed at the end of this leaflet.
- you are allergic to prostaglandins
- your pregnancy is near full term.
- you have previously experienced a difficult labour. or delivery.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you have:

- given birth more than twice
- uterine scarring
- cervical narrowing
- vaginal bleeding of unknown origin
- had a twin pregnancy
- an infection of the cervix or vagina
- a respiratory condition
- any heart condition
- glaucoma or increased eye pressure
- allergies to any other medicines, any other substances, such as foods, preservatives or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

CERVAGEM is not to be used to soften the cervix or to induce labour in the pregnant woman at term.

3. What if I am taking other medicines?

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

Some medicines may interfere with CERVAGEM and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CERVAGEM.

4. How do I use CERVAGEM?

How to use

- CERVAGEM is administered by insertion via the vagina by a doctor or nurse.

5. What should I know while using CERVAGEM?

Things you should do

Call your doctor straight away if you experience:

- asthma, wheezing or shortness of breath, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, hives, itching, skin
- rash or fainting. These are symptoms of an allergic reaction.
- chest spasm or pain.
- prolonged or spasmodic pelvic/lower back pain
- bleeding

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

Remind any doctor, dentist or pharmacist you visit that you are using CERVAGEM.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how CERVAGEM affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Store below -10°C (freeze) in the original pack.
- Remove only sufficient pessaries from freezer for immediate use. Any pessaries removed from freezer should NOT be refrozen.

Keep it where young children cannot reach it.

When to discard your medicine

Once the foil sachet has been opened, any pessary not used within 12 hours should be destroyed.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
General • slight fever • flushing • chills • headache • dizziness • lightheadedness **Gastrointestinal related** • nausea, vomiting **Respiratory** • shortness of breath **Musculoskeletal** • lower abdominal pain • backache • muscle weakness • vaginal bleeding or uterine pain **Cardiovascular** • Irregular heart beats	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Allergic reactions • asthma, wheezing or shortness of breath • swelling of the face, lips or tongue which may cause difficulty swallowing or breathing • itching, hives, skin rash • fainting • chest spasm or pain	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of**
• prolonged or spasmodic pelvic/ lower backpain	**these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What CERVAGEM contains

Active ingredient (main ingredient)	gemeprost 1 mg
Other ingredients (inactive ingredients)	ethanol and hard fat
Potential allergens	ethanol

Do not take this medicine if you are allergic to any of these ingredients.

What CERVAGEM looks like

CERVAGEM is a white to creamy torpedo shaped pessary. (Aust R 27491).

Who distributes CERVAGEM

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Freecall No: 1800 818 806

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