CERVIDIL® (ser-vi-dil)

Dinoprostone (also known as prostaglandin E_2 or PGE_2) 10 mg pessary (vaginal insert)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CERVIDIL®.

It does not contain all the available information.

It does not take the place of talking to your doctor or midwife.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given CERVIDIL® against the benefits he/she expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or midwife.

Keep this leaflet in a safe place.

You may need to read it again.

What CERVIDIL® is used for

CERVIDIL® is for women who have a normal pregnancy and are near their due date for delivery. It is used to prepare for induction.

CERVIDIL® is a pessary (vaginal insert) containing dinoprostone, also known as Prostaglandin E_2 or PGE_2. Prostaglandin E_2 also occurs naturally in the body. Prostaglandin E_2 is important for the changes that take place before labour begins.

CERVIDIL® is used to prepare the cervix (the neck of the womb, at the top of the birth canal) to allow the baby to pass through. This process is called “cervical ripening”.

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

Your doctor may have prescribed CERVIDIL® for another purpose.

Ask your doctor or midwife if you have any questions about why CERVIDIL® has been prescribed for you.

How it works

CERVIDIL® works by

- softening and opening the cervix (neck of the womb).
- setting off contractions (in the body of the womb)
- releasing dinoprostone continuously to the cervix at the appropriate rate

This allows softening and opening of the cervix to progress.

When the doctor decides no further dinoprostone is required, the pessary (vaginal insert) is removed by pulling on the withdrawal tape.

Before you are given CERVIDIL®

Your doctor will decide if CERVIDIL® is suitable for you.

CERVIDIL® should be administered only by trained personnel, in hospital, with appropriate obstetrical care and facilities for the required monitoring.

When you must not be given it

You must not be given CERVIDIL® if you have an allergy to dinoprostone or any of the ingredients (eg. urethane) 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.

You must not be given CERVIDIL® if

- you are carrying more than one baby
- your labour has already started
- there is any reason why you should not have a vaginal delivery, for example, genital herpes
- the baby's head is not well down in the pelvis
- the baby is not in the normal position for birth *or*
- if it is suspected, or tests show, your baby is unwell or not growing *or*
- the head of the baby is too big or the size of your pelvis is too small for normal delivery *or*
- you have contractions that are unusually strong and/or long (known as "hypertonic contractions" or "hyper- stimulation of the uterus").

You must not be given CERVIDIL® if you have had any of the following:

- previous surgical operation on the womb, for example, a caesarean section *or*
- surgery to the neck of the womb (cervix) *or*
- previous rupture of the cervix
- any vaginal discharge or unexplained vaginal bleeding during the current pregnancy

You must not be given CERVIDIL® if you have untreated pelvic inflammatory disease (also known as PID); usually caused by an infection of the internal female sex organs; it may result in, for example, pain and tenderness of the stomach and fever.

You should not be given CERVIDIL®

- if the packaging is torn or shows signs of tampering
- after the expiry date (EXP) printed on the pack

If you are not sure whether you should be given CERVIDIL®, talk to your doctor.

Before you start to take it

Tell your doctor or midwife if you are taking/using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines and CERVIDIL® may interfere with each other.

Your doctor or midwife may have more information on medicines to be careful with or avoid while using CERVIDIL®.

You must not be given CERVIDIL® if you are being given, or are to be given intravenously within the next thirty minutes, medicines to make the muscles of your womb contract or bring on labour, eg. oxytocin.

Medication with aspirin and other non-steroidal anti-inflammatory drugs (known as NSAIDs) should be stopped before administration of CERVIDIL®. Some examples of NSAIDS are Naprosyn and Voltaren.

Tell your doctor or midwife if your have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

Before you are given CERVIDIL® tell your doctor or midwife if you are over 35 years of age or if you have or have had any medical conditions, especially the following:

- lung, liver or kidney problems
- asthma
- epilepsy (convulsions or fits)
- unexplained genital bleeding during current pregnancy
- glaucoma (raised pressure in the eye)
- abnormally strong contractions of your womb during a previous labour or
- previous excessively short labour and delivery time
- heart or blood pressure problems
- previous complications during pregnancy
- you have had more than three full term deliveries
- gestational diabetes
- your pregnancy is past 40 weeks gestation
- your waters have broken

When CERVIDIL® must be removed

The pessary (vaginal insert) should be removed immediately

- if contractions are considered too sustained or excessive *or*
- if labour commences

It should also be removed

- prior to amniotomy
- after the waters break (spontaneous rupture of the membranes)
- if there is any suggestion of maternal or fetal complications *or*
- if unwanted side-effects occur
- if after 24 hours the cervix has not changed adequately for delivery.

How CERVIDIL® is given

How much is given

CERVIDIL® is given as one pessary (vaginal insert), inserted once only.

Each CERVIDIL® insert contains 10 mg dinoprostone.

Over the maximum recommended usage period of 24 hours, the insert gradually releases about 0.3 mg of dinoprostone per hour.

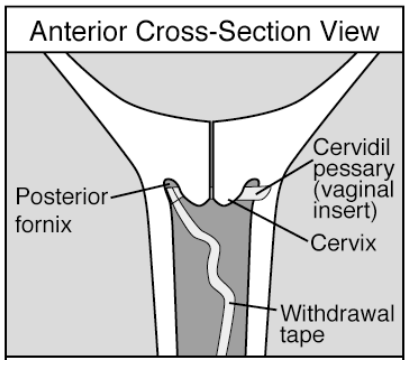
How it is given

CERVIDIL® must only be given under the supervision of a doctor.

CERVIDIL® is inserted into the vagina. The pouch containing the active ingredient is positioned up at the top of the vagina behind the cervix. This is called the "posterior fornix" (See Figure 1).

The tape for withdrawal hangs from the entrance to the vagina.

Figure 1



Before CERVIDIL® is used, careful assessment of the cervix is necessary.

After insertion of CERVIDIL® the following must be monitored regularly:

- changes in the cervix
- presence or absence of contractions
- frequency, duration and strength of contractions
- fetal condition
- baby's health

If there is any suggestion of maternal or fetal complications, or if adverse effects occur, the CERVIDIL® pessary (vaginal insert) should be removed. This is done by gently pulling on the withdrawal tape, until the whole device is removed from the vagina.

Administration

CERVIDIL® looks like a small slim tampon, with a very long attached tape. CERVIDIL® must not be used without this tape, which is used to withdraw the pessary (vaginal insert).

Your doctor or midwife will coat the CERVIDIL® with a little lubricating jelly before putting it in your vagina. The tampon-like end, which holds the medicine, is placed behind the neck of the womb (cervix), in the area know as the "posterior fornix" of the vagina. The medicine gradually passes from the device into the upper vagina. The continuing concentration of medicine in the fluids around the cervix causes the cervix to become softer and gradually open.

The attached withdrawal tape is left hanging out of the entrance to your vagina. Your doctor or midwife can therefore easily pull out the CERVIDIL® pessary (vaginal insert) when it is time to do so, or if it needs to be removed for any reason.

While you are being given CERVIDIL®

Things you must do

You will be lying down while CERVIDIL® is put in. You should remain lying down for at least 30 minutes afterwards. Your doctor or midwife will advise you when you can get up again. The pessary (vaginal insert) should be left in place for no longer than 24 hours.

While the pessary (vaginal insert) is in place, you will be checked frequently. Examples of what is being checked include but are not limited to,

- the neck of the womb (cervix),
- the strength and frequency of any contractions,
- the health of your unborn baby

Removal

The pessary (vaginal insert) is removed by gently pulling the withdrawal tape.

How long it is used for

Your doctor or midwife will remove the pessary (vaginal insert) when you no longer need it or after 24 hours.

For example, they may remove it because:

- your labour has started
- your doctor wants to use a different medicine to help your womb (uterus) contract eg. oxytocin
- your waters have broken
- your uterus is contracting too strongly
- your baby is starting to get distressed.

Overdosage

Your medical attendants will be alert for any signs of overdose. Your doctor, midwife or pharmacist have information on how to recognise and treat an overdose. Initial treatment of overdose is removal of the pessary (vaginal insert). Other treatment is also available.

Contact the Poisons Information Centre on 0800 POISON (0800 764 766) for further advice on overdose management.

Side effects

Tell your doctor or midwife as soon as possible, if you do not feel well while you are being given CERVIDIL®.

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

In most people, CERVIDIL® helps prepare the cervix (neck of womb) for the birth. It may have unwanted side effects in a few people.

Tell your doctor or midwife immediately if you notice any of the following:

- headache
- dizziness

- itching
- diarrhoea
- bleeding, possibly from multiple sites of your body
- fever
- nausea or vomiting
- very strong or, very frequent contractions of the womb.
- bluish coloration of the fingers
- sudden bruising

The above list includes serious side effects. Your doctor may decide to remove the CERVIDIL® pessary (vaginal insert) if these side effects occur.

Tell your doctor or midwife if you notice any other side effects.

Rarely, rupture of the womb has been reported in association with the use of CERVIDIL®. However, most of these patients should not have been given CERVIDIL®. See the section beginning **"When you must not be given it"** above.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or midwife to answer any questions you may have.

Storage of CERVIDIL®.

Before use

CERVIDIL® is kept in a freezer and removed immediately before use. It is stored in the hospital.

Keep Cervidil® out of reach of children.

Note the expiry on the pack. Do not use after this expiry date.

Disposal

The used pessary (vaginal insert) should be disposed of as clinical waste.

Product description

What it looks like

The CERVIDIL® pessary (vaginal insert) is

- a thin, flat rectangle, with rounded corners
- slightly thicker than a large postage stamp
- beige in colour
- contained within a pouch
- made so that, when the pouch becomes moist, the active ingredient (dinoprostone) comes out very slowly. The pouch forms one end of a long tape
- pouch and tape are made of knitted polyester (off-white in colour)
- tape allows withdrawal of the insert at the end of dosing.

NOTE: After recommended use, when CERVIDIL® is removed from the vagina, the tampon-like end will have become larger. It absorbs fluid and becomes 2-3 times its original size.

Ingredients

The active ingredient in CERVIDIL® is dinoprostone.

The active ingredient is within a plastic (polyurethane) sustained release insert which contains: hexanetriol/macrogol 8000/isocyanate cross-linked hydrogel copolymer.

The insert is held within a pouch in continuity with a withdrawal tape. Pouch and tape are made of knitted polyester yarn.

Presentation

CERVIDIL® is in an aluminium/ polyethylene foil sachet, each containing 1 pessary (vaginal insert).

Further information

You can obtain more information from your doctor or pharmacist.

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