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CERVIDIL

Dinoprostone

Vaginal delivery system 10 mg

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vaginal delivery system consists of a non-biodegradable polymeric drug delivery device containing 10 mg dinoprostone (Prostaglandin E_2) dispersed throughout its matrix.

CERVIDIL is a thin, flat, semi-transparent polymeric slab which is rectangular in shape with rounded corners contained within a knitted polyester retrieval system.

Each insert contains 10 mg dinoprostone (prostaglandin E_2) dispersed throughout its matrix, and releases approximately 0.3 mg/hour PGE_2 over a 24 hour period. The reservoir of 10 mg dinoprostone serves to maintain constant release. The retrieval system consists of a one-piece knitted polyester pouch and withdrawal tape. This ensures easy and reliable removal of the insert when the patient's requirement for PGE_2 has been fulfilled or an obstetric event makes it necessary to stop further drug administration.

Each insert contains 10 mg of dinoprostone in 236 mg of a cross-linked polyethylene oxide/urethane polymer which is a semi-transparent, beige coloured, flat, 0.8 mm thick rectangular slab measuring 29 mm by 9.5 mm. The insert and its retrieval system, made of polyester yarn, are non-toxic and when placed in a moist environment, absorb water, swell, and release dinoprostone.

Excipients: Crosslinked macrogol (hydrogel) [Ph. Eur.] /Crosslinked polyethylene glycol (hydrogel) [USP]; Polyester yarn

PHARMACEUTICAL FORM

Vaginal delivery system

CERVIDIL is presented as a thin, flat, semi-transparent polymeric vaginal delivery system which is rectangular in shape with rounded corners contained within a knitted polyester retrieval system.

THERAPEUTIC INDICATIONS

CERVIDIL Vaginal Delivery System (dinoprostone 10 mg) is indicated for initiation and/or continuation of cervical ripening in patients at or near term (from 37 completed weeks of gestation) in whom there is a medical or obstetrical indication for the induction of labor.
CERVIDIL should be administered only by trained obstetrical personnel in a hospital setting with appropriate obstetrical care facilities.

POSOLOGY AND METHOD OF ADMINISTRATION

Posology

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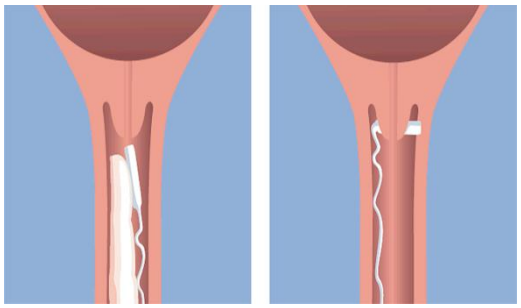
CERVIDIL should only be administered by qualified healthcare personnel in hospitals and clinics with obstetric units with facilities for continuous fetal and uterine monitoring.

After insertion, uterine activity and fetal condition must be carefully and regularly monitored.

One vaginal delivery system is administered high into the posterior vaginal fornix.



The vaginal delivery system should be removed after 24 hours irrespective of whether cervical ripening has been achieved.

In case of subsequent administration of uterotonic drugs, a dosing interval of at least 30 minutes is recommended following the removal of the vaginal delivery system.

Paediatric population
The safety and efficacy of CERVIDIL in pregnant woman aged less than 18 years has not been established. No data are available.

Method of administration
Administration

CERVIDIL should be removed from the freezer just prior to the insertion. No thawing is required prior to use.

There is a "tear mark" on side of the foil sachet. Open the package along the tear mark across the top of the sachet. Do not use scissors or other sharp objects which may cut the retrieval system.

The vaginal delivery system should be inserted high into the posterior vaginal fornix using only small amounts of water soluble lubricants to aid insertion. After the vaginal delivery system has been inserted, the withdrawal tape may be cut with scissors always ensuring there is sufficient tape outside the vagina to allow removal. No attempt should be made to tuck the end of the tape into the vagina as this may make retrieval more difficult.

The patient should be recumbent for 20 minutes to 30 minutes after insertion. As dinoprostone will be released continuously over a period of 24 hours, it is important to monitor uterine contractions and fetal condition at frequent regular intervals.

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Removal

The vaginal delivery system can be removed quickly and easily by gentle traction on the retrieval tape.

It is necessary to remove the vaginal delivery system to terminate drug administration when cervical ripening is judged to be complete or for any of the reasons listed below.

1. Onset of labour. For the purposes of induction of labour with CERVIDIL, the onset of labour is defined as the presence of regular painful uterine contractions occurring every 3 minutes irrespective of any cervical change. There are two important points to note:
   i. Once regular, painful contractions have been established with CERVIDIL they will not reduce in frequency or intensity as long as CERVIDIL remains in situ because dinoprostone is still being administered.
   ii. Patients, particularly multigravidae, may develop regular painful contractions without any apparent cervical change. Effacement and dilatation of the cervix may not occur until uterine activity is established. Because of this, once regular painful uterine activity is established with CERVIDIL in-situ, the vaginal delivery system should be removed irrespective of cervical state to avoid the risk of uterine hyperstimulation.
2. Spontaneous rupture of the membranes or amniotomy.
3. Any suggestion of uterine hyperstimulation or hypertonic uterine contractions.
4. Evidence of fetal distress.
5. Evidence of maternal systemic adverse dinoprostone effects such as nausea, vomiting, hypotension or tachycardia.
6. At least 30 minutes prior to starting an intravenous infusion of uterotonic drugs.

The opening on one side of the retrieval device is present only to allow the manufacturer to enclose the vaginal delivery system into the retrieval device during manufacture. The vaginal delivery system should NEVER be removed from the retrieval device.

Upon removal of the product from the vagina, the vaginal delivery system will have swollen 2-3 times its original size and be pliable.

CONTRAINDICATIONS

CERVIDIL should not be used or left in place:

1. When labour has started.
2. When uterotonic drugs and/or other labour induction agents are being given.
3. When strong prolonged uterine contractions would be inappropriate such as in patients:
   a. who have had previous major uterine surgery, e.g. caesarean section, myomectomy (see sections SPECIAL WARNINGS AND PRECAUTIONS FOR USE and UNDESIRABLE EFFECTS)
   b. who have had previous major uterine cervix surgery (e.g. other than biopsies and cervical abrasion) or rupture of the uterine cervix
   c. with cephalopelvic disproportion
   d. with fetal malpresentation

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e. with suspicion or evidence of fetal distress

4. When there is current pelvic inflammatory disease, unless adequate prior treatment has been instituted.
5. When there is hypersensitivity to Prostaglandin E_2 or to any of the excipients listed in section QUALITATIVE AND QUANTITATIVE COMPOSITION.
6. When there is placenta previa or active herpes genitalis or unexplained vaginal bleeding during the current pregnancy.
7. When the patient is carrying more than one fetus or the fetus is in a non-vertex presentation
8. When there is abnormal cardiotocograpy or suspected fetal compromise.
9. In the presence of any suggestion of uterine hyperstimulation or hypertonic uterine contractions.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

The condition of the cervix should be assessed carefully before CERVIDIL is used. After insertion, uterine activity and fetal condition must be monitored carefully and regularly by qualified healthcare personnel. CERVIDIL must only be used in hospitals and clinics with obstetric units with facilities for continuous fetal and uterine monitoring. If there is any suggestion of maternal or fetal complications or if adverse effects occur, the vaginal delivery system should be removed from the vagina.

Uterine rupture has been reported in association with the use of CERVIDIL, mainly in patients with contra-indicated conditions (see section CONTRAINDICATIONS). Therefore, CERVIDIL should not be administered to patients with a history of previous caesarean section or uterine surgery given the potential risk for uterine rupture and associated obstetrical complications.

If uterine contractions are prolonged or excessive, there is possibility of uterine hypertonus or rupture and the vaginal delivery system should be removed immediately.

A second dose of CERVIDIL is not recommended, as the effects of a second dose have not been studied.

CERVIDIL should be used with caution in patients with a previous history of uterine hypertonus, glaucoma or asthma.

The experience of CERVIDIL in patients with ruptured membranes is limited. Therefore, CERVIDIL should be used with caution in those patients. Since the release of dinoprostone from the insert can be affected in the presence of amniotic fluid, special attention should be given to uterine activity and fetal condition.

Women aged 35 and over, women with complications during pregnancy, such as gestational diabetes, arterial hypertension and hypothyroidism, and women at gestational age above 40 weeks have a higher post partum risk for developing disseminated intravascular coagulation (DIC). These factors may additionally enhance the risk of disseminated intravascular coagulation in women with pharmacologically induced labour (see section UNDESIRABLE EFFECTS). Therefore, dinoprostone should be used with caution in these women. In the immediate post-partum phase the physician should look out carefully for early signs of a developing DIC (e.g fibrinolysis).

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The Clinician should be alert that, as with other labour induction methods, use of dinoprostone may result in inadvertent abruption of placenta and subsequent embolization of antigenic tissue causing in rare circumstances the development of Anaphylactoid Syndrome of Pregnancy (Amniotic Fluid Embolism).

CERVIDIL should be used with caution when there is a multiple pregnancy. No studies in multiple pregnancy have been performed.

CERVIDIL should be used with caution when the woman has had more than three full term deliveries. No studies in woman with more than three full term deliveries have been performed.

The use of the product in patients with diseases which could affect the metabolism or excretion of dinoprostone, e.g. lung, liver or renal disease, has not been specifically studied. The use of the product in such patients is not recommended.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
No dedicated interaction studies have been performed with CERVIDIL

Prostaglandins potentiate the uterotonic effect of uterotonic drugs. Therefore, CERVIDIL should not be used concurrently with the use of uterotonic drugs.

Medication with non-steroidal anti-inflammatory drugs, including acetylsalicylic acid, should be stopped before administration of dinoprostone.

FERTILITY, PREGNANCY AND LACTATION
Pregnancy

CERVIDIL is for the initiation of cervical ripening in pregnant patients at term (from 37 completed weeks) only where labour induction is indicated.

CERVIDIL is not indicated for use in pregnancy prior to 37 completed weeks of gestation.

Breast-feeding
No studies have been performed to investigate the amount of dinoprostone in colostrum or breast milk following the use of CERVIDIL.

Dinoprostone may be excreted in colostrum and breast milk, but the level and duration is expected to be very limited and should not hinder breastfeeding. No effects on the breastfed newborns have been observed in the clinical studies conducted.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
Not relevant.

UNDESIRABLE EFFECTS

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Summary of safety profile:

The most commonly reported adverse drug reactions in placebo-controlled and active comparator efficacy clinical trials (N=1116) were "fetal heart rate disorder" (6.9%), "uterine contractions abnormal" (6.2%) and "abnormal labour affecting fetus" (2.6%).

The table below displays the main ADRs distributed by system organ classes (SOC) and frequency. Further, the ADRs seen during post-marketing experience are mentioned with unknown frequency.

Adverse reactions observed in clinical studies are presented according to their incidence, post authorisation reported adverse reactions are presented in the column frequency unknown.

System organ class	**Common (≥ 1/100 and < 1/10)**	**Uncommon (≥ 1/1000 and ≤ 1/100)**	**Frequency unknown**
Blood and lymphatic system disorders			Disseminated intravascular coagulation
Immune system disorders			Anaphylactic reaction Hypersensitivity
Nervous system disorders		Headache	
Cardiac disorders	Fetal heart rate disorder [1*]		
Vascular disorders		Hypotension	
Respiratory, thoracic and mediastinal disorders		Neonatal respiratory distress related conditions	
Gastrointestinal disorders			Abdominal pain Nausea, vomiting, diarrhoea
Hepatobiliary disorders		Neonatal hyperbilirubinaemia	
Skin and subcutaneous tissue disorders		Pruritus	

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Pregnancy, puerperium and perinatal conditions	Abnormal labour affecting fetus [2*] Uterine contractions abnormal, uterine tachysystole, uterine hyperstimulation, uterine hypertonus Meconium in amniotic fluid	Postpartum haemorrhage Premature separation of placenta Apgar score low Arrested labour Chorioamnionitis Uterine atony	Anaphylactoid syndrome of pregnancy Fetal distress syndrome [3*] Fetal death, stillbirth, neonatal death [4*]
Reproductive system and breast disorders		Vulvovaginal burning sensation	Genital oedema
General disorders and administration site conditions		Febrile disorders	
Injury, poisoning and procedural complications			Uterine rupture

1* "Fetal heart rate disorder" was in clinical studies reported as "fetal heart rate abnormalities", "fetal bradycardia", "fetal tachycardia", "unexplained absence of normal variability", "fetal heart rate decreased", "fetal heart rate deceleration", "early or late decelerations", "variable decelerations", "prolonged decelerations".
2* "Abnormal labour affecting fetus" as expression for hyperstimulation syndrome was in clinical studies reported as "uterine tachysystole" combined with "late decelerations", "fetal bradycardia", or "prolonged decelerations"
3* "Fetal distress syndrome" was also reported as "fetal acidosis" , "pathological CTG", "fetal heart rate abnormalities", "intrauterine hypoxia" or "threatening asphyxia". The term itself is unspecific, has a low positive predictive value and is often associated with an infant who is in good condition at birth.
4* Fetal death, stillbirth, and neonatal death have been reported after application of dinoprostone, especially following the occurrence of serious events such as uterine rupture (see sections POSOLOGY AND METHOD OF ADMINISTRATION, CONTRAINDICATIONS and SPECIAL WARNINGS AND PRECAUTIONS FOR USE).

Adverse Event Reporting

If you notice any of the adverse events reactions mentioned above, or any adverse reactions not listed in this leaflet, please contact your doctor or nurse. You can also report these side effects to Ferring or the national reporting system provided below. Reporting side effects helps to gather more information about the safety of this medication.

PT Ferring Pharmaceuticals Industry
Safety Mailbox Indonesia
No Telp: (021) 50868801
Email: SafetyMaliboxIndonesia@ferring.com

Pusat MESO/Farmakovigilans Nasional

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Direktorat Pengawasan Keamanan, Mutu dan Ekspor Impor Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif
Badan POM RI
Jl. Percetakan Negara 23 Jakarta Pusat, 10560
No Telp: 021 – 4244691 Ext.1079
Email: pv-center@pom.go.id
Web : http://e-meso.pom.go.id/

OVERDOSE
Overdosage may lead to hyperstimulation of the uterine muscle with or without fetal distress. If fetal distress occurs, remove CERVIDIL immediately and manage in accordance with local protocol.

PHARMACODYNAMIC PROPERTIES
Pharmacotherapeutic group: uterotonics, prostaglandins, ATC-code: G02AD02

Prostaglandin E_2 (PGE_2) is a naturally occurring compound found in low concentrations in most tissues of the body. It functions as a local hormone.

PGE_2 plays an important role in the complex set of biochemical and structural alterations involved in cervical ripening. Cervical ripening involves a transformation of the uterine cervix which must be transformed from a rigid structure to a soft, dilated configuration to allow passage of the fetus through the birth canal. This process involves activation of the enzyme collagenase which is responsible for the breakdown of the collagen.

Local administration of dinoprostone to the cervix results in cervical ripening which then induces the subsequent events which complete labour.

PHARMACOKINETIC PROPERTIES
PGE_2 is rapidly metabolised primarily in the tissue of synthesis. Any which escapes local inactivation is rapidly cleared from the circulation with a half-life generally estimated as 1-3 minutes.

No correlation could be established between PGE_2 release and plasma concentrations of its metabolite, PGE_m. The relative contributions of endogenously and exogenously released PGE_2 to the plasma levels of the metabolite PGE_m could not be determined.

The reservoir of 10 mg dinoprostone serves to maintain a controlled and constant release. The release rate is approximately 0.3 mg per hour over 24 hours in women with intact membranes whereas release is higher and more variable in women with premature rupture of membranes. CERVIDIL releases dinoprostone to the cervical tissue continuously at a rate which allows cervical ripening to progress until complete, and with the facility to remove the dinoprostone source when the clinician decides that cervical ripening is complete or labour has started, at which point no further dinoprostone is required.

PRECLINICAL SAFETY DATA
Preclinical studies have demonstrated that dinoprostone is a locally acting substance which is rapidly

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inactivated in the vagina, and thus has no significant systemic exposure and hence no evidence of toxicity.

The hydrogel polyurethane and polyester polymers which are the constituents of the release method for dinoprostone and the retrieval device, respectively, showed no adverse effects in toxicity studies, and both were found to have no local tolerance problems. In addition, the hydrogel was negative in a test to identify potential for causing toxic shock syndrome.

Reproduction toxicity, genotoxic or carcinogenic effects of the polymers have not been investigated but systemic exposure is negligible.

INCOMPATIBILITIES
Not applicable.

SHELF LIFE
3 years.

STORAGE
Store in a freezer (between -10°C and -20°C). Store in the original container in order to protect from moisture.

SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING
CERVIDIL should be removed from the freezer just prior to the insertion. After usage, the whole product should be disposed of as clinical waste.

PACKING SIZE
Box of 1 Vaginal Delivery System @ 10 mg (Reg. No.: DKI2255800192A1)

MANUFACTURED BY
Ferring Controlled Therapeutics Ltd
Scotland, United Kingdom

SECONDARY PACKAGING BY
Ferring Controlled Therapeutics Limited
1 Redwood Place, Peel Park Campus, East Kilbride, Glasgow, G74 5PB
12 Redwood Crescent, Peel Park Campus, East Kilbride, Glasgow, G74 5PA
United Kingdom

IMPORTED BY
PT Ferring Pharmaceuticals Industry
Tangerang Selatan – Indonesia

HARUS DENGAN RESEP DOKTER

DATE OF REVISION
25 Nov 2025

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Informasi untuk pasien
CERVIDIL 10 mg *Vaginal Insert*
Dinoprostone

Bacalah seluruh isi leaflet ini dengan seksama sebelum Anda diberikan CERVIDIL karena leaflet ini berisi informasi penting untuk Anda.

- Simpanlah leaflet ini, sebab Anda mungkin perlu membacanya lagi dikemudian hari.
- Apabila Anda memiliki pertanyaan lebih lanjut, tanyakan pada dokter, bidan atau perawat Anda.
- Jika Anda mengalami efek samping, beritahukan dokter, bidan atau perawat Anda. Termasuk efek samping yang mungkin tidak tercantum dalam leaflet ini. Lihat bagian 4.
- CERVIDIL sebaiknya hanya digunakan di bawah pengawasan dokter spesialis yang sesuai

Apa yang ada di leaflet ini:

1. Apa CERVIDIL itu dan digunakan untuk apa

CERVIDIL mengandung zat aktif dinoprostone 10 mg dan digunakan untuk membantu mulainya proses kelahiran dengan syarat bahwa usia kehamilan telah melewati 37 minggu. Dinoprostone membuka bagian dari jalan lahir yang dikenal sebagai leher rahim (serviks), untuk memudahkan bayi melewatinya. Ada beberapa alasan mengapa Anda mungkin perlu bantuan memulai proses ini. Tanyakan kepada dokter Anda jika Anda ingin tahu lebih lanjut.

2. Apa yang perlu Anda ketahui sebelum Anda diberikan CERVIDIL

Jangan menggunakan CERVIDIL

Anda tidak boleh diberikan CERVIDIL:

- Jika ukuran kepala bayi Anda dapat menyebabkan masalah selama persalinan
- Jika bayi Anda tidak dalam posisi yang benar di dalam rahim, untuk dilahirkan secara alami
- Jika bayi Anda tidak sehat dan/atau dalam kesusahan
- Jika Anda pernah menjalani operasi besar sebelumnya atau ruptur serviks
- Jika Anda memiliki penyakit radang panggul yang tidak dirawat (ada infeksi di rahim, indung telur, tuba fallopi dan/atau leher rahim)
- Jika plasenta menghalangi jalan lahir
- Jika Anda mengalami atau pernah mengalami perdarahan vagina yang tidak jelas selama kehamilan ini

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- Jika Anda sebelumnya pernah menjalani operasi rahim termasuk kelahiran Caesar pada bayi sebelumnya
- Jika Anda hipersensitif (alergi) terhadap dinoprostone atau salah satu zat lain dari CERVIDIL (tercantum di bagian 6).

Dokter atau perawat tidak akan memberi Anda CERVIDIL atau akan menghentikan penggunaannya:
- Setelah persalinan dimulai
- Jika Anda perlu diberikan obat misalnya oxytocic untuk membantu membantu proses persalinan Anda
- Jika kontraksi Anda terlalu kuat atau berkepanjangan
- Jika bayi Anda menjadi tertekan (dalam kesusahan)
- Jika Anda mengalami efek samping (lihat bagian 4. Efek samping yang mungkin terjadi).

Hanya ada sedikit kasus mengenai penggunaan Cervidil jika air ketuban Anda sudah pecah. Dokter atau perawat Anda akan mengeluarkan CERVIDIL yang telah diberikan kepada Anda jika air ketuban Anda pecah atau akan dipecahkan oleh dokter atau perawat.

Peringatan dan tindakan pencegahan
Sebelum Anda diberikan CERVIDIL, harap beri tahu dokter atau perawat Anda jika hal-hal berikut berlaku/terjadi pada Anda:
- Jika Anda saat ini menderita atau pernah menderita asma (kesulitan bernapas) atau glaukoma (suatu gangguan mata)
- Jika Anda pernah menderita kontraksi yang terlalu kuat atau berkepanjangan pada kehamilan sebelumnya
- Jika Anda menderita penyakit paru-paru, hati atau ginjal
- Jika Anda akan melahirkan lebih dari satu bayi
- Jika Anda sudah mengalami lebih dari tiga persalinan cukup bulan
- Jika Anda sedang meminum obat nyeri dan/atau peradangan, yang mengandung obat anti-inflamasi non-steroid (juga dikenal sebagai NSAID) mis. aspirin
- Jika Anda berusia 35 tahun atau lebih, jika Anda mengalami komplikasi selama kehamilan, seperti diabetes, tekanan darah tinggi dan kadar hormon tiroid rendah (hipotiroidisme), atau jika kehamilan di atas 40 minggu karena peningkatan risiko berkembangnya diseminasi koagulasi intravaskular (DIC), suatu gangguan langka yang mempengaruhi pembekuan darah.

Anak-anak dan remaja
Penggunaan CERVIDIL pada anak-anak dan remaja di bawah usia 18 tahun belum diteliti.

Obat-obat lain dan CERVIDIL
Katakan kepada dokter atau perawat Anda jika Anda sedang atau baru saja minum obat lain, termasuk obat-obat bebas yang didapat tanpa resep.
CERVIDIL dapat membuat Anda lebih sensitif terhadap obat-obatan yang termasuk golongan obat oksitosik yang digunakan untuk memperkuat kontraksi. Tidak dianjurkan untuk memberikan obat-obat ini bersamaan dengan CERVIDIL.

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Kehamilan dan menyusui
CERVIDIL digunakan untuk membantu memulai proses kelahiran pada masa bulannya. CERVIDIL tidak boleh digunakan pada waktu lain selama kehamilan.
Penggunaan CERVIDIL selama menyusui belum diteliti. CERVIDIL dapat diekskresikan dalam ASI tetapi jumlah dan durasinya diperkirakan akan terbatas dan tidak menghalangi pemberian ASI. Tidak ada efek yang teramati terhadap bayi baru lahir yang disusui.

Berkendara dan menggunakan mesin
Tidak relevan karena CERVIDIL digunakan dalam kaitannya dengan persalinan saja.

3. Bagaimana cara pemberian CERVIDIL

CERVIDIL hanya boleh diberikan oleh petugas kesehatan yang memiliki kualifikasi di rumah sakit dan klinik yang memiliki unit kebidanan dengan fasilitas pemantauan janin dan rahim secara terus menerus.

Dokter atau perawat akan menempatkan satu sistem pemberian obat melalui vagina di dekat mulut rahim/servik di dalam vagina Anda. Anda tidak boleh melakukan tindakan ini sendiri. Dokter atau perawat Anda akan melapisi sistem pemberian obat melalui vagina dengan sedikit jeli pelumas sebelum siap untuk digunakan. Pita yang cukup panjang akan ditinggalkan di luar vagina, untuk memudahkan pengeluaran sistem pemberian obat melalui vagina ini bila diperlukan.
Anda harus berbaring selama prosedur ini dan Anda harus tetap seperti itu selama sekitar 20-30 menit setelah insersi/penempatan CERVIDIL.

Ketika ditempatkan di posisinya, sistem pemberian obat melalui vagina ini menyerap kelembapan di dalam vagina. Ini akan memungkinkan dinoprostone untuk dilepaskan secara bertahap.
Sementara sistem pemberian obat melalui vagina ini sudah siap digunakan untuk membantu untuk memulai persalinan Anda, Beberapa pemeriksaan akan dilakukan secara berkala , seperti:

- bukaan serviks Anda
- kontraksi uterus/rahim
- Rasa sakit saat persalinan dan kesehatan bayi Anda yang berkelanjutan

Dokter atau perawat akan memutuskan berapa lama pemberian CERVIDIL perlu dipertahankan digunakan, tergantung pada kemajuan Anda. CERVIDIL dapat dibiarkan di tempat selama maksimal 24 jam.
Pada saat pelepasan produk dari vagina, sistem penyaluran ke vagina ini akan membengkak hingga 2-3 kali dari ukuran aslinya dan sifatnya lentur.

Jika Anda telah diberikan CERVIDIL untuk waktu yang lebih lama dari yang seharusnya
Jika Anda telah diberikan CERVIDIL untuk waktu yang lebih lama dari yang seharusnya, hal itu dapat menyebabkan peningkatan kontraksi atau bayi dapat menjadi tertekan. Jika demikian, sistem penyaluran obat ke vagina CERVIDIL harus segera dilepaskan.

4. Efek samping yang mungkin terjadi

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Changes		
Reference	☐ CCDS version: ☐Core PIL version:	☒SPC country/version/date: UK PIL ☐LAC no.:
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Seperti semua obat, CERVIDIL dapat menyebabkan efek samping, meskipun tidak semua orang mengalaminya.

Umum: dapat dialami 1 dari 10 orang
Peningkatan kontraksi rahim yang kemungkinan bisa mempengaruhi bayi.

- Bayi bisa menjadi tertekan dan/atau detak jantungnya bisa menjadi lebih cepat atau lebih lambat dari biasanya.
- Cairan ketuban berubah warna.

Tidak umum: dapat dialami 1 dari 10 orang

- Sakit kepala
- Penurunan tekanan darah
- Bayi yang baru lahir mengalami kesulitan bernapas begitu dilahirkan
- Bayi yang baru lahir memiliki kadar bilirubin darah tinggi, rusaknya produk sel darah merah, yang dapat menyebabkan kulit dan mata menjadi kuning.
- Gatal
- Perdarahan vagina berat setelah/paska persalinan
- Plasenta terlepas dari dinding rahim sebelum bayi dilahirkan
- Kondisi bayi baru lahir secara keseluruhan tertekan begitu dilahirkan
- Perkembangan yang lambat dalam proses persalinan
- Radang selaput yang melapisi bagian dalam rahim
- Rahim ibu tidak mengkerut setelah melahirkan karena kurangnya kontraksi uterus yang normal
- Merasa terbakar di area genital
- Demam

Tidak diketahui: frekuensi tidak dapat diperkirakan dari data yang tersedia

- Kematian janin, lahir mati dan kematian bayi baru lahir (neonatal death); terutama mengikuti peristiwa serius seperti robeknya rahim
- *Disseminated Intravascular Coagulation* (DIC), gangguan langka yang mempengaruhi pembekuan darah. Ini dapat menyebabkan pembentukan pembekuan darah dan dapat meningkatkan risiko perdarahan.
- Cairan yang mengelilingi bayi selama kehamilan dapat memasuki aliran darah ibu saat kelahiran dan menghambat pembuluh darah yang menyebabkan gangguan yang disebut sindrom anafilaktoid kehamilan, yang dapat mencakup, gejala seperti: sesak napas, tekanan darah rendah, kecemasan dan menggigil ; masalah yang mengancam jiwa dengan pembekuan darah, kejang-kejang, koma, perdarahan dan cairan di paru-paru dan tekanan ke janin seperti detak jantung yang lambat.
- Reaksi hipersensitivitas dan reaksi alergi berat (reaksi anafilaksis), yang dapat meliputi: sulit bernafas, sesak napas, nadi lemah atau cepat, pusing, gatal, kemerahan pada kulit dan ruam.
- Sakit perut
- Mual
- Muntah
- Diare
- Pembengkakan area genital
- Robeknya rahim

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Pelaporan Kejadian yang Tidak Diinginkan (Adverse Event Reporting)
Jika Anda mengalami salah satu reaksi yang tidak diinginkan seperti yang disebutkan di atas, atau reaksi yang tidak tercantum dalam leaflet ini, harap segera hubungi dokter atau perawat Anda. Anda juga dapat melaporkan efek samping tersebut kepada Ferring atau sistem pelaporan nasional yang tercantum di bawah ini. Pelaporan efek samping membantu mengumpulkan lebih banyak informasi mengenai keamanan obat ini.

PT Ferring Pharmaceuticals Industry
Safety Mailbox Indonesia
No. Telp: (021) 50868801
Email: SafetyMaliboxIndonesia@ferring.com

5. Bagaimana cara menyimpan CERVIDIL

Jauhkan obat ini dari pandangan dan jangkauan anak-anak. Jangan gunakan CERVIDIL setelah tanggal kedaluwarsa yang tercantum pada kantong sachet foil dan kartonnya.
Simpan dalam freezer (-10°C hingga -20°C). Simpan dalam wadah aslinya agar terlindung dari kelembaban. Obat ini tidak boleh dibuang melalui air limbah atau limbah rumah tangga. Setelah penggunaan, dokter atau perawat Anda akan membuang seluruh produk sebagai limbah klinis. Langkah-langkah ini akan membantu melindungi lingkungan.

6. Isi kemasan dan informasi lainnya

Apa isi CERVIDIL
- Zat aktifnya adalah dinoprostone, lebih dikenal sebagai Prostaglandin E_2. Setiap sistem pemberian obat melalui vagina mengandung 10 mg dinoprostone yang dilepaskan sekitar 0,3 mg per jam selama waktu 24 jam.
- Bahan lainnya adalah *crosslinked macrogol* (hidrogel) dan *polyester yarn*.

Tampilan CERVIDIL dan bagaimana isi kemasannya
Sistem pemberian obat melalui vagina berupa sepotong plastik kecil berbentuk oval yang terkandung dalam sistem penarikan rajutan.
Potongan plastik berupa suatu polimer hidrogel yang membengkak dengan adanya kelembaban untuk melepaskan dinoprostone.
Sistem penarikan ini memiliki pita panjang yang membuat dokter atau perawat dapat mengeluarkannya sewaktu diperlukan.
Setiap sistem pemberian obat melalui vagina ditempatkan dalam suatu kantong sachet foil tertutup yang diproduksi dari strip laminasi aluminium/polyethylene foil dan dikemas dalam suatu karton.

KEMASAN
Box of 1 Vaginal Delivery System @ 10 mg (Reg. No.: DKI2255800192A1)

Pemegang Hak Pemasaran dan Produsen
Diproduksi oleh:
Ferring Controlled Therapeutics Ltd

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Scotland, United Kingdom

Diimpor oleh:
PT. Ferring Pharmaceuticals Industry
Tangerang Selatan – Indonesia

HARUS DENGAN RESEP DOKTER

Leaflet ini terakhir direvisi pada 25 November 2025