Cervagem®

Gemeprost pessary

1 mg

SANOFI

Please read this leaflet carefully BEFORE you are given GEMEPROST pessary 1.0mg. This leaflet is a summary of important information about your pessaries. If you have any questions, or are not sure about anything to do with your treatment, ask your doctor, or nurse for more information.

PRESENTATION AND COMPOSITION

White to yellowish-white spindle shaped vaginal pessaries each containing 1mg GEMEPROST. Also contains Witepsol S52 and dehydrated ethanol 1.25%v/w.

INDICATIONS

1. Softening and dilatation of the *cervix uteri* prior to trans-cervical intrauterine operative procedures in pregnant patients in the first trimester of gestation.
2. Therapeutic termination of pregnancy in patients in the second trimester of gestation, in licensed institutions.
3. Induction of abortion of second trimester pregnancies complicated by intrauterine foetal death.

ADMINISTRATION AND DOSAGE

Before administration, the pessary should be allowed to warm to room temperature for 30 minutes, away from direct heat and sunlight, in the unopened foil sachet.

1. Softening and dilatation of the cervix in the first trimester of gestation.

Adults: One pessary to be inserted into the posterior vaginal fornix 3 hours before surgery.

2. Therapeutic termination of pregnancy in the second trimester of gestation.

Adults: One pessary to be inserted into the posterior vaginal fornix at **3-hourly** intervals to a maximum of 5 administrations.
If abortion is not established after 5 pessaries, a second course of treatment may be instituted starting 24 hours after the initial commencement of treatment.
Vaginal bleeding and uterine contractions may start after the administration of the first or second pessary, but treatment should be continued for the full course unless complete abortion occurs earlier.
The embryopathic hazards of gemeprost have not been determined. Every effort should be made to ensure that once treatment has started termination of the pregnancy is completed.
If abortion is not well established after 10 pessaries, a further course of GEMEPROST treatment is not recommended and alternative means should be employed to effect uterine emptying.

3.Intrauterine foetal death in the second trimester of gestation.

One pessary to be inserted into the posterior vaginal fornix at 3-hourly intervals up to a maximum of 5 administrations.
Elderly: Not applicable.
Children: Not applicable.

CONTRAINDICATIONS

GEMEPROST should not be administered to women with known hypersensitivity to prostaglandins or to women with renal function disturbances. GEMEPROST is also contraindicated in women experiencing uterine fragility related to uterine scarring, and in placenta previa.
GEMEPROST pessaries should not be used for the induction of labour or cervical softening at term as foetal effects have not been ascertained.

PRECAUTIONS

GEMEPROST should be used with caution in patients with obstructive airways disease, those with cardiovascular insufficiency, elevated intraocular pressure, cervicitis or vaginitis.
Serious, potentially fatal, cardiovascular accidents (myocardial infarction and/or spasm of the coronary arteries and severe hypotension) have been reported with prostaglandins including GEMEPROST. Cardiac and vascular parameters should be monitored by taking regular measurements of the patient's pulse and blood pressure.
There have been reports of uterine rupture with gemeprost. Therefore, extreme care must be taken and cervical dilatation and uterine contractions monitored, when using this drug in the termination of preg-

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TYPE OF MATERIAL: LEAFLET FOLDED	DESCRIPTION: CERVAGEM 1 MG	COUNTRY: MALAYSIA/SINGAPORE	LOGO VERSION: //	MIN. FONT SIZE: 8.5 pt.			
CODE: 826281 89036898	VERSION: 1 a	OLD CODE: 759836 89034752	DIE CUT: I003	DIMENSIONS mm: 125 x 210 (125 x 26,25)	COLOURS N°: 1	COLOUR 1: REFLEX BLUE	

nancy (whether therapeutic or for intrauterine foetal death) especially during the second trimester or the second course of therapy. This is particularly important in women who have one or more of the following conditions: multiparity, uterine scarring, cervical stenosis, vaginal bleeding of unknown origin, or twin pregnancy.
Coagulopathy may occur following intrauterine foetal death and should be monitored and managed actively according to current clinical standard practice.
Adequate follow up of a patient having a pregnancy terminated is essential to ensure that the process has been completed, as the embryopathic hazards of GEMEPROST have not been determined.
Patients with the following diseases have not been studied: ulcerative colitis; diabetes mellitus; sickle-cell anaemia; epilepsy; disorders of blood coagulation; cardiovascular or pulmonary disease.
When used for cervical dilatation, if it is necessary to postpone surgery for much beyond the recommended 3 hour interval patients should be kept under observation, as there is a possibility that spontaneous abortion may occur.
GEMEPROST pessaries should not be used for the induction of labour or cervical softening at term as foetal effects have not been ascertained.

INTERACTIONS
Oxytocin and other labour inducers or accelerators can potentiate the action of GEMEPROST.

SIDE-EFFECTS
Vaginal bleeding and mild uterine pain, similar to menstrual pain, may occur in the interval between the administration of the pessary and surgery, especially if this interval is prolonged beyond the recommended 3 hours. Nausea, vomiting, loose stools or diarrhoea may occur but are rarely severe enough to require treatment.
However, standard anti-emetic or anti-diarrhoeal agents may be administered if required.
Other reported side-effects include headache, muscle weakness, dizziness, flushing, chills, backache, dyspnoea, chest pain, palpitations and mild pyrexia.
Uterine rupture has been reported on rare occasions, most commonly in multiparous women and in those women with a history of uterine surgery.
Anaphylactic reactions have not occurred with GEMEPROST but such reactions have very rarely been noted with other prostaglandins.
In very rare cases, severe hypotension and coronary spasms with subsequent myocardial infarctions have been reported.

OVERDOSAGE
The toxic dose of GEMEPROST in women has not been established. Cumulative dosage of 10mg in 24 hours was accompanied by a significant increase in incidence and severity of side-effects. In animals the acute toxic effects are similar to those of prostaglandin E1 and include relaxation of smooth muscle, leading to hypotension and depression of the CNS. **Clinically valuable signs of impending toxicity are likely to be sedation, tremor, convulsion, dyspnoea, abdominal pain and diarrhoea, which may be bloody, palpitations or bradycardia. Treatment should be symptomatic. A vaginal douche may be of value depending on the elapsed time since insertion of the pessary.**

PHARMACODYNAMIC PROPERTIES
Gemeprost (16, 16-dimethyl-trans-delta2 PGEI methyl ester) is a prostaglandin E1 analogue. Both in pregnant and non-pregnant animals, it causes contraction of the uterus and causes softening and decreases resistance of cervical tissue. Gemeprost depresses placental and uterine blood flow but those actions are secondary to the main uterine stimulation. In women, gemeprost is an effective cervical dilator in the first trimester in pregnancy, gemeprost is also effective at terminating pregnancy in the second trimester of gestation.

PHARMACOKINETIC PROPERTIES
In pregnant women, although plasma levels of both the active drug and the main metabolite (de-esterified gemeprost) are very low, gemeprost induces cervical softening within three hours of insertion.
Between 12 and 28% of the vaginal dose is eventually absorbed into the circulation, and 50% of this is excreted in the urine. The unabsorbed dose is largely recovered from the genital area, either washed out in the urine or from pads used to absorb postoperative blood loss.

STORAGE PRECAUTIONS
Store below minus 10°C (-10°C) in the original pack. Temperature cycling should be avoided.
Once the foil sachet has been opened, any pessary not used within 12 hours should be destroyed.

Nature and contents of container
Container of 5 unit dose foil pessaries.

Batch released by:
SANOFI S.R.L.
Via Valcanello 4
03012 Anagni, Italy

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