Package leaflet: information for the user

MISOFAR 25 micrograms vaginal tablets

Misoprostol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Misofar 25 is and what it is used for

Misofar 25 consists of vaginal tablets which belong to the group of medicines called prostaglandins. Specifically, it is a synthetic analogue of prostaglandin E_1.

Misofar 25 is an uterotonic agent indicated for cervical ripening and the induction of labour at term, especially in cases of unripe cervix, and as long as there are no foetal or maternal contraindications.

2. What you need to know before you use Misofar 25

Do not use Misofar 25
- if you are allergic to misoprostol, to prostaglandins or to any of the other ingredients of this medicine (listed in section 6);
- if you cannot be administered drugs containing oxytocin or if prolonged uterine contractions are considered inappropriate;
- if you have any of the following characteristics:
  - History of caesarean section or major uterine surgery
  - Cephalopelvic disproportion
  - Situations of foetus in transverse lie
  - Suspicion or clinical evidence of pre-existing foetal distress
  - History of difficulty and/or traumatic childbirth
  - Multiparous women, with six or more previous term pregnancies
  - In obstetric emergencies, when the benefit-risk ratio for the foetus and for the mother justifies surgical intervention
  - Multiple pregnancy
  - Unexplainable vaginal discharge and/or irregular uterine haemorrhage during the current pregnancy

- if vaginal delivery is contraindicated, such as cases of placenta praevia or active genital herpes;
- if there are risk factors of suffering amniotic fluid embolism, pre-eclampsia or eclampsia;
- if you are simultaneously administered oxytocin or other uterine contraction stimulants.

Warnings and precautions
Talk to your doctor, pharmacist or midwife before using Misofar 25.
Tell your doctor:
- if you have blood coagulation problems or suffer from anaemia;
- if you suffer from malnutrition;
- if you are epileptic or have a history of epileptic episodes;
- if you have any kidney, liver, heart or arteries illnesses;
- if you have low pressure (hypotension);
- if you have rupture of membranes;
- if you suffer from infection of the placental membranes and of the amniotic fluid (chorioamniotitis), pregnancy disorder called hydatidiform mole and/or intrauterine foetal death.

Before using Misofar 25:
- Cephalopelvic indexes must be carefully measured.

Before and during use of Misofar 25:
- The cervix must be assessed by performing normal gynaecological procedures, such as vaginal-abdominal palpation.
- Uterine activity and foetal status must be closely monitored in order to detect possible evidence of undesirable responses such as hypertonus, sustained uterine contractility or foetal distress.
- In the event of patients developing uterine hypercontractility or hypertonus (increased contractions or uterine tone), or if the foetal heartbeat is not adequate, one must proceed so as not to cause risk to the mother or foetus.
  Like with other uterotonic agents, the risk of uterine rupture, especially if there is prior uterine scarring, should taken into account.

An increased risk of postpartum disseminated intravascular coagulation (severe bleeding) has been described in patients whose labour has been induced by some method.

Other medicines and Misofar 25
Tell your doctor or pharmacist if you are using, have recently used, or might use any other medicine.

Some medicines may interact with Misofar 25, such as anticoagulants (acenocumarol), antacids which contain magnesium, anti-inflammatory (NSAIDs) and laxatives.

Misoprostol may increase the effect of oxytocin (a drug that favours the onset and work of labour by stimulating contractions). The simultaneous administration of oxytocin along with other medicines which stimulate uterine contractions is contraindicated. In the event of there being a need to administer misoprostol and oxytocin consecutively, in the doctor’s opinion, the patient's uterine activity must be closely monitored.

Misofar 25 with food and drink
There are no known interactions of Misofar 25 with food and drink.

Pregnancy and breastfeeding
If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Misofar 25 is used to help start labour from week 37 of pregnancy. When used at that time of pregnancy there is no risk of birth defects for your baby. However, you should not use Misofar 25 at any other time during pregnancy because misoprostol can then cause birth defects.

Misoprostol is excreted in breast milk, but its concentration is insignificant 5 hours after it has been administered.

Driving and using machines
No effects on driving or using machines have been observed.

Misofar 25 contains hydrogenated castor oil, which may cause skin reactions. Even though the amount contained in the preparation is probably insufficient to trigger this effect, this must be taken into account.

3. How to use Misofar 25

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will indicate the duration of the treatment with Misofar 25, as well as the dose with which the treatment will begin and how it will continue.

The recommended dose is one 25 microgram tablet of misoprostol every 4-6 hours, up to a maximum of 4 to 6 tablets.
The dose must be adapted to the patient's response and must always be maintained at the lowest levels which cause a satisfactory uterine response.

The route of administration for Misofar 25 is vaginal.

You will lay down on a gynaecological examination table and the doctor or midwife will administer the tablets by inserting them into your vagina, having previously washed their hands with care.

If you feel that the action of Misofar 25 is too strong or weak, inform your doctor.

Children and adolescents
Misofar 25 has not been studied in women under 18 years of age.

If you use more Misofar 25 than you should
An overdose may manifest by means of hypertonic uterine contractions (with the risk of foetal death in uterus), hyperthermia (increase of temperature), tachypnea (increase of respiratory rate), hypotension (low blood pressure), convulsions with chills, agitation and emesis (vomiting).

If uterine activity or side effects reach excessive intensity, the dosage will be reduced or treatment will be suspended and the administration of a symptomatic treatment will be considered.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or midwife.

4. Possible side effects

Like all medicines, Misofar 25 can cause side effects, although not everybody gets them.

The most serious side effects that may arise are the following: drug hypersensitivity, uterine rupture and cardiac arrest.

The most common side effects are:

- Gastrointestinal disorders: nausea, vomiting, diarrhoea and abdominal pain (stomachache).

Other occasional side effects are:
- Immune system disorders: hypersensitivity reactions (allergies).
- Psychiatric disorders: syncope (fainting), neurosis.
- Nervous system disorders: dizziness, confusion, drowsiness (sleepiness), headache, trembling, anxiety.
- Eye disorders: visual disorders and conjunctivitis (eye infection).
- Cardiac disorders: hypertension (high blood pressure), hypotension (low blood pressure), cardiac arrhythmia (alteration of heartbeat).
- Vascular disorders: phlebitis (inflammation of the veins), oedema (swelling), thromboembolism (formation of blood clots in the blood vessels).
- Respiratory, thoracic and mediastinal disorders: coughing, dyspnoea (breathing difficulties), bronchitis, pneumonia, epistaxis (nasal bleeding).
- Skin and subcutaneous tissue disorders: skin rash (reddening), exanthematous eruption (skin allergy), dermatitis (skin inflammation), alopecia (hair loss).
- Musculoskeletal disorders: athralgia (joint pain), myalgia (muscles pain), cramps and muscular stiffness, back pain.
- Renal and urinary disorders: There have been cases of polyuria (increased urinary frequency) and haematuria (blood in urine).
- Pregnancy, puerperium (weeks after delivery) and perinatal conditions: abnormal uterine contractility (increased frequency, tone or duration) with or without foetal bradycardia (slower heartbeat), uterine rupture, premature membrane rupture, premature detachment of the placenta, amnionitis (infection of the amniotic fluid), pulmonary embolism (blood clots) due to amniotic fluid, vaginal haemorrhage (bleeding).
- Reproductive system and breast disorders: dysmenorrhoea (painful menstruation) and vaginal haemorrhage (bleeding) appear rarely.
- General disorders and administration site conditions: transient hyperthermia (increased body temperature), chills.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Spanish System of Pharmacovigilance for Medicinal Products for Human Use: https://www.notificaram.es. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Misofar 25

This medicinal product does not require any special storage conditions.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the package after “CAD”. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Place containers and medicines no longer used in Used Medicines Collection Point (known in Spain as Punto SIGRE ) in a pharmacy.

Ask your pharmacist how to throw away contaniners and medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Misofar 25 contains

- The active substance is misoprostol. Each vaginal tablet contains 25 micrograms of misoprostol.
- The other ingredients (excipients) are: hydroxypropyl methylcellulose, microcrystalline cellulose, sodium starch glycolate (type A) and hydrogenated castor oil.

What Misofar 25 looks like and contents of the pack

Misofar 25 are white, round vaginal tablets with a cross-shaped mark on one side. They are available in cartons with 8 vaginal tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Laboratorios BIAL, S.A.
C/ Alcalá 265, Edificio 2, Planta 2ª
28027 Madrid
Spain

Manufacturer:
INDUSTRIA QUÍMICA Y FARMACÉUTICA VIR, S.A:
C/ Laguna 66-68-70. Polígono Industrial Urtinsa II
28923 Alcorcón (Madrid)-Spain

Local representative:
Exeltis Healthcare, S.L.
Avda. de Miralcampo, 7
Polígono Industrial Miralcampo
19200 Azuqueca de Henares
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Detailed and updated information on this medicine is available on the website of the Spanish Agency for Medicines and Healthcare Products (AEMPS) http://www.aemps.gob.es/