Package leaflet: information for the user

MISOFAR 200 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 200 is and what it is used for

Misofar 200 consists of vaginal tablets which belong to the group of medicines called prostaglandins. Specifically, it is a synthetic analogue of prostaglandins E_1.

Misofar 200 is indicated:
- for cervical priming in non-pregnant women before a diagnostic hysteroscopy and/or surgery, or other gynaecological procedures requiring access to the uterine cavity.
- management of spontaneous or induced abortion incomplete without complications, in monotherapy or in association with mifepristone.

The decision about the mode of management of incomplete abortion should be based on the individual's clinical condition and preference for treatment.

2. What you need to know before you use Misofar 200

Do not use Misofar 200
- 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 oxytocic drugs or if prolonged uterine contractions are considered inappropriate;
- for the expansion of non-gravid uterine cervix before a hysteroscopy or other gynaecological procedures requiring access to the uterine cavity: if you are pregnant or think you are;
- for management of spontaneous abortion incomplete and induced abortion incomplete: Known or suspected ectopic pregnancy.

Warnings and precautions
Talk to your doctor or pharmacist before using Misofar 200.

Tell your doctor:

- if you have blood clotting problems or suffer from anaemia;
- if you suffer from malnutrition;
- if you have a history of caesarean section or major uterine surgery;
- if you have epilepsy or previous history of epileptic episodes;
- if you have any kidney, liver, heart or arteries illnesses;
- if you have low pressure (hypotension).

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

The administration between mifepristone and misoprostol should be spaced 1-2 days, according to available information. For more information, consult the package leaflet of medicines containing mifepristone.

The risk of uterine rupture increases with gestational age. Uterine rupture is a rare complication; clinical judgement and health system preparedness for emergency management of uterine rupture must be considered with advanced gestational age.

After treatment, uterine bleeding will appear, which can last up to 2-3 weeks (usually an average of 9 days), and can be more or less intense. Your doctor will inform you how to manage the bleeding. If the bleeding is very heavy and/or prolonged, consult your doctor.

Other medicines and Misofar 200
Tell your doctor or pharmacist if you are using, have recently used, or might use any other medicine.

Some medicines may interact with Misofar 200, such as anticoagulants (acenocoumarol), antacids which contain magnesium, anti-inflammatory (NSAIDs) and laxatives.

Misofar 200 with food and drink
There are no known interactions of Misofar 200 with food and drink.

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

When used as recommended, clinical effects are unlikely to occur, as Misofar 200 shall only be administered to women of childbearing age who are not pregnant and/or to postmenopausal women.

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 200 contains hydrogenated castor oil which may cause allergic reactions on the application area.

3. How to use Misofar 200

Always use this medicine exactly as your doctor 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 200, as well as the dose with which the treatment will begin and how it will continue.

For the expansion of non-gravid uterine cervix before a hysteroscopy or other gynaecological procedures requiring access to the uterine cavity, the recommended dose is 400 micrograms of misoprostol. In cases without a medical history of previous caesarean or uterine scarring, it should be administrated in the uterus from 2 to 8 hours before. In cases with a medical history of previous caesarean or uterine scarring, it should be administrated in the uterus from 2 to 4 hours before.

- For the medical management of incomplete abortion with an uterine size lower than 14 weeks: use of 600 µg misoprostol, in monotherapy or 1-2 days after administration of mifepristone. Depending on clinical assessment and the different local recommendations or protocols 800 µg misoprostol may also be used. If necessary, additional doses can be administered after 24 hours.

- For the medical management of incomplete abortion with an uterine size of 14 weeks or higher: use of 400 µg misoprostol every three hours, in monotherapy or 1-2 days after administration of mifepristone. Misoprostol can be repeated at the noted interval as needed to achieve success of the abortion process.

Your doctor will decide, at gestational ages higher than 14 weeks, the maximum number of doses if you have a previous uterine incision.

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 administration route of Misofar 200 is vaginal.

Follow the recommendations of use below:
- Carefully wash your hands.
- Take the vaginal tablet out from the blister.
- Lie on your back with your legs touching your chest.
- With the tip of your middle finger, place the vaginal tablet into your vagina as deep as possible without causing discomfort.

If you feel that the action of Misofar 200 is too strong or weak, inform your doctor or pharmacist.

Children and adolescents
Misofar 200 has not been studied in women under 18 years of age.

If you use more Misofar 200 than you should
If you have used more tablets than your doctor has indicated, check with your doctor or pharmacist immediately, go to the nearest hospital or call the Poison Information Service (Servicio de Información Toxicológica) on 91 562 04 20, indicating the medicine and the amount administrated.

Overdose may manifest by means of uterine contractions (with the risk of intrauterine foetal death), hyperthermia (an increase in temperature), tachypnea (increase of respiratory rate), hypotension (low blood pressure), convulsions with chills, agitation and emesis (vomiting).

In the event of substantial overdose, supportive treatment will be symptomatic.

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

4. Possible side effects

Like all medicines, Misofar 200 can cause side effects, though 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:
- Infections and infestations: Infection of the uterus (endometritis and pelvic inflammatory disease),
- Gastrointestinal disorders: nausea, vomiting, diarrhoea and abdominal pain (stomachache).

Other occasional side effects are:
- Infections and infestations: Generalized infection (sepsis) and septic shock.
- Blood and lymphatic system disorders: anaemia.
- 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 fever (increased body temperature), chills and malaise.

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 200

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 containers and medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Misofar 200 contains

- The active substance is misoprostol. Each vaginal tablet contains 200 micrograms of misoprostol.
- The other ingredients (excipients) are: hydroxypropyl methylcellulose, microcrystalline cellulose, sodium starch glycolate (type A), and hydrogenated castor oil.

What Misofar 200 looks like and contents of the pack

Misofar 200 are white, oblong capsular shaped, scored vaginal tablets. There are 4 vaginal tablets in each pack.

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

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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/