MISODEL®

Modified release pessary (vaginal insert)
misoprostol 200 micrograms

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MISODEL vaginal insert.

The leaflet does not contain all the available information.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you using MISODEL vaginal insert against the benefits s/he expects it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet.
You may need to read it again.

What MISODEL is used for

MISODEL vaginal insert contains the active substance misoprostol.

MISODEL vaginal insert is used to help induce labour (i.e. start the birth process) when it is necessary from 36 weeks of pregnancy in women where the cervix (neck of the uterus) is insufficiently soft, thin and dilated to ease the passage of the baby.

Misoprostol belongs to a group of medicines called prostaglandins. Prostaglandins have two actions during labour. One is to soften the cervix to ease the birth of the baby through the vagina. The second is to cause contractions to start, which will help push the baby out of the uterus. There could be several reasons for deciding to induce labour.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

MISODEL vaginal insert is available only with a doctor's prescription.

This medicine is not addictive.

Before you are given MISODEL

Your doctor will decide if MISODEL vaginal insert is suitable for you.

MISODEL vaginal insert should only be administered by trained obstetric personnel, in hospitals where continuous electronic monitoring of the unborn baby and of contractions of the uterus is available. The hospital must have readily available facilities for emergency Caesarean delivery.

When MISODEL must not be given

You must not be given MISODEL vaginal insert if you have an allergy to:

- any medicine containing misoprostol
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- skin rash, itching or hives
- swelling of the face, lips, tongue or other parts of the body
- shortness of breath, wheezing or difficulty breathing.

You must not be given MISODEL vaginal insert in the following situations:

- if the hospital in which you are giving birth does not have appropriate personnel, obstetric care and facilities for the required monitoring and management of you and your baby
- if you are pregnant with more than one baby (e.g. twins)
- if you have previously had more than 3 babies delivered vaginally after 24 weeks of pregnancy
- if you have had previous surgery to your cervix or uterus, including a previous Caesarean delivery for any earlier babies
- if your unborn baby is not in good health and/or is distressed
- if your unborn baby is large for its gestational age
- if your unborn baby is not in the correct position in the womb to be born naturally
- if you have any womb abnormality such as 'heart-shaped' uterus
- if the amniotic fluid volume is less than it should be
- if you have any signs or symptoms of infection of the membranes that surround your unborn baby, unless adequate treatment has already been given
- if your placenta is covering the birth canal or if you have had any unexplained vaginal bleeding after the 24th week of this pregnancy
- if you are less than 36 weeks pregnant
- if contractions are becoming regular
- if oxytocic drugs (medicines used to ease birth) and/or other medicines to induce labour are being given.

MISODEL vaginal insert is used to help start labour from week 36 of the pregnancy. MISODEL vaginal insert should not be used at other phases of pregnancy.

MISODEL vaginal insert should not be given to you after the expiry date on the pack has passed.
If you use this medicine after the expiry date has passed, it may not work.

MISODEL vaginal insert should not be given to you if the packaging is torn or shows signs of tampering or the product does not look quite right.

If it has expired or is damaged, it should be returned to a pharmacist or doctor for disposal.

If you are not sure whether you should be given MISODEL vaginal insert, talk to your doctor.

Before you are given MISODEL

Your doctor or midwife will carefully monitor and assess you and your unborn baby before MISODEL vaginal insert is inserted.

This can involve the use of an electronic monitor to measure the activity (contractions) of your uterus and your unborn baby's heartbeat. The position of your unborn baby will be assessed. A vaginal examination will also be performed to determine the status of the cervix before MISODEL vaginal insert is inserted.

Tell your doctor or midwife if you have high blood pressure.
MISODEL vaginal insert has not been used in women with high blood pressure (severe pre-eclampsia).

Tell your doctor or midwife if you think your waters might have broken (premature rupture of your membranes).
MISODEL vaginal insert has not been studied in women whose waters have been broken for more than 48 hours prior to insertion of MISODEL vaginal insert.

Tell your doctor or midwife if you have an infection with Group B Streptococcus that requires preventive antibiotic therapy.
The antibiotic treatment may be given to you at the same time as MISODEL vaginal insert or earlier so that you and your baby are treated before the birth.

Tell your doctor or midwife if you are pregnant with more than one baby (e.g. twins).
There is no experience with the use of MISODEL vaginal insert to start the birth process in women who are pregnant with more than one baby.

Tell your doctor if you are planning to breast-feed your baby.
There is very little information about the effect of MISODEL on breastfed babies.

Tell your doctor if you are less than 18 years of age.
MISODEL has not being studied in this population.

Also for your information:
An increased risk of severe bleeding after delivery has been described in patients whose labour has been induced by any method.

Tell your doctor or midwife if:

- you have allergies to any other medicines
- you have allergies to any other substances, such as foods, preservatives or dyes.

If you have not told your doctor or midwife about any of the above, tell them before you are given MISODEL vaginal insert.

Taking other medicines

Tell your doctor or midwife if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with misoprostol.

MISODEL vaginal insert must not be given if you are already receiving oxytocic drugs (medicines used to ease birth) and/or other medicines to help induce labour.

If you have been given MISODEL vaginal insert and your doctor decides that treatment with these medicines is needed, MISODEL vaginal insert must be removed at least 30 minutes beforehand.

Your doctor or midwife has more information on medicines to be careful with or avoid while using MISODEL vaginal insert.

How MISODEL is given

How much is given

The recommended dose is one MISODEL vaginal insert.

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

MISODEL vaginal insert can be left in place for up to 24 hours but will need to be removed earlier in many women (e.g. when labour commences). The doctor or midwife will decide how long MISODEL vaginal insert will be kept in place, depending on your progress.

How it is given

The instructions on how to use MISODEL vaginal insert are included in the carton.

Your doctor or midwife may coat MISODEL vaginal insert with a small amount of lubricating jelly before putting the vaginal insert in place.

Your doctor or midwife will place one MISODEL vaginal insert in your vagina and place it next to the cervix (Figure A). You will not do this yourself. They will position the insert so that it will remain in place (Figure B).

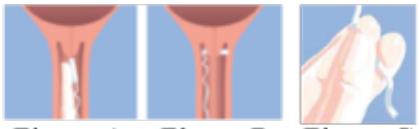

Figure A Figure B Figure C

The tail of the tape which encloses the MISODEL vaginal insert will be positioned so it is accessible for later removal.

Removal

Your doctor or midwife will remove MISODEL by gently pulling the tail of the retrieval system (Figure C).

The vaginal insert should NEVER be removed from the retrieval tape.

While you are being given MISODEL

Things you must do

You will be lying down while MISODEL is being inserted and you will have to stay that way for about 30 minutes after insertion of MISODEL vaginal insert.

Once placed in the vagina, MISODEL vaginal insert takes up moisture, swells up and slowly releases misoprostol.

While the vaginal insert is in place, you will be checked frequently.

Examples of what may be checked include but are not limited to:

- the cervix to see if it is softening and dilating
- the strength and frequency of any contractions
- the health of your unborn baby. This will include monitoring your unborn baby's heart rate.

Things to be careful of

When using the toilet, please be careful to avoid removing MISODEL vaginal insert by mistake.

Tell the doctor or midwife if MISODEL vaginal insert falls out at any time.

How long is it used for

The doctor or midwife will decide how long MISODEL vaginal insert will be kept in place, depending on your progress.

MISODEL vaginal insert can be left in place for up to 24 hours. If MISODEL vaginal insert falls out, it should not be replaced.

The vaginal insert should be removed:

- when labour starts when contractions are becoming regular
- if your contractions are too strong, prolonged or too frequent
- if your unborn baby becomes distressed
- if 24 hours have elapsed since insertion
- if you or your unborn baby experience a concerning adverse event.

In case the contractions of the uterus are prolonged or strong or your doctor or midwife is concerned for you or your unborn baby, MISODEL vaginal insert will be removed. If the contractions continue after removal of MISODEL vaginal insert, anti-contraction treatment may be given, which in most cases will resolve the contractions.

Do not remove MISODEL vaginal insert yourself.

Your doctor or midwife will remove the vaginal insert by gently pulling the retrieval tape.

On removal of the product from the vagina, MISODEL vaginal insert will have swollen to 2-3 times its original size and be flexible.

MISODEL vaginal insert can cause strong stimulation of the uterus if left in place after onset of labour (see Side effects below).

If you use too much (overdose):

Your doctor or midwife will be alert for any signs of overdose.

If MISODEL vaginal insert is left in place after onset of labour it may lead to increasing contractions and the unborn baby may become distressed.

Your doctor or midwife has information on how to recognise and treat an overdose. Initial treatment of overdose is removal of the vaginal insert.

Other treatment is also available. Contact the Poisons Information Centre (telephone 13 11 26) 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 receiving MISODEL vaginal insert.

This medicine helps women to start the birth process from 36 weeks of pregnancy, but it may have unwanted side effects. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

- very strong or, very frequent contractions of the womb or a contraction that lasts too long and may be a reason for concern
- a decrease in movements of your unborn baby
- unborn baby's heart rate changes during labour which may be a reason for concern
- mother's womb contracts too frequently and the unborn baby's heart rate may be affected which may be a reason for concern
- evidence of stained amniotic fluid. This can happen if an unborn baby passes a bowel motion (meconium) into the amniotic fluid, which becomes stained yellow, brown or green, and can be a sign of distress.

The above list includes the very common side effects (may affect at least 1 in 10 people).

Your doctor or midwife may decide to remove MISODEL vaginal insert if any of these side effects occur.

If any of the following happen, tell your doctor or midwife immediately:

- the baby has difficulty breathing or is breathing rapidly immediately after birth
- excessive vaginal bleeding after birth
- overall newborn condition depressed at birth (e.g. pale or blue colour, poor responses, limp)
- increased acidity in blood of the newborn baby (fetal acidosis)
- pain that lasts between contractions
- irregular contractions that are too strong, prolonged or too frequent
- unexpected bleeding from the vagina before delivery.

The above list includes common side effects (may affect at least 1 in 100 people) and may require medical attention.

Other side effects not listed above may also occur in some patients. These can include:

- vomiting
- nausea
- increase in blood pressure
- red skin rash
- itching of the genital area
- tearing of the womb
- brain affected in the baby due to not enough oxygen
- unexpected bleeding from the vagina before delivery
- the placenta separates from the wall of the womb before the birth of the baby.

The above list includes the uncommon side effects (may affect at least 1 in 1000 people) and may require medical attention.

Tell your doctor or midwife if you notice anything that is making you feel unwell.

There are no data on long-term outcomes for babies following use of MISODEL vaginal insert.

Ask your doctor or midwife if you do not understand anything in this list.

Do not be alarmed by the lists of side effects.

You may not experience any of them.

Storage and disposal of MISODEL

Storage

This medicine should be kept in a freezer where the temperature stays below -18°C.

This medicine should be kept in its original packaging until it is time to be used.

No thawing is required prior to use.

Controlled periods of time of up to one week at 2 to 8°C can be allowed within the shelf-life of the product.

Once the MISODEL insert is removed from the freezer it may be stored for a period of up to one week in the refrigerator (2 to 8°C) prior to use. However, if the insert is not used during this period of storage in the refrigerator, it should be discarded, and must not be returned to the freezer for later use. If stored in the refrigerator, the date of removal from the freezer should be noted.

Keep it where children cannot reach it.

Disposal

The used MISODEL vaginal insert should be disposed of as clinical waste.

Product description

What it looks like

MISODEL vaginal insert is packed in an individual, sealed laminated aluminium foil sachet.

Each vaginal insert is a thin, flat rectangle, with rounded corners, beige in colour.

The vaginal insert is enclosed in a pouch on the end of a long tape: pouch and tape are made of knitted polyester (off-white in colour). The tape allows withdrawal of the insert at the end of dosing.

When the vaginal insert becomes moist the active ingredient (misoprostol) is released slowly.

MISODEL vaginal inserts are supplied in packs of 1s or 5s. Not all pack sizes may be marketed.

Ingredients

Active ingredient:

- misoprostol.

Inactive ingredients:

- hexanetriol/macrogol 8000/isocyanate cross-linked hydrogel copolymer
- butylated hydroxyanisole (antioxidant).

Sponsor

MISODEL vaginal inserts are supplied in Australia by:

Ferring Pharmaceuticals Pty Ltd
Suite 2, Level 1, Building 1
20 Bridge Street
Pymble, NSW 2073

This leaflet was prepared in April 2018.

#32934-v4B

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