

Package leaflet: Information for the user

MisoOne 400 microgram tablets

Misoprostol

Read all of this leaflet carefully before you start taking 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.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What MisoOne is and what it is used for
2. What you need to know before you take MisoOne
3. How to take MisoOne
4. Possible side effects
5. How to store MisoOne
6. Contents of the pack and other information

1. What MisoOne is and what it is used for

MisoOne tablets contain misoprostol, which is similar to a chemical substance called ‘prostaglandin’ that your body produces naturally. Misoprostol triggers contractions of the womb and softens the cervix.

For medical termination of pregnancy: MisoOne is used after taking another medicine called mifepristone. It should be taken no later than 49 days after the first day of your last menstrual period.

For surgical termination of pregnancy: MisoOne is taken on its own prior to surgical termination of pregnancy during the first trimester of pregnancy (within 12 weeks after the first day of your menstruation).

2. What you need to know before you take MisoOne

Do not take MisoOne

- if you are allergic to misoprostol, any other prostaglandin or any of the other ingredients of this medicine (listed in section 6).
- if the pregnancy has not been confirmed by ultrasound scan or biological tests.
- if your doctor suspects an ectopic pregnancy (the egg is implanted outside the womb).
- if you cannot take mifepristone (when mifepristone is used in combination with MisoOne).
- for medical termination of pregnancy, if the first day of your last period was more than 49 days (7 weeks) ago.

Warnings and precautions

Talk to your doctor before taking MisoOne

- if you have liver or kidney disease
- if you suffer from anaemia or malnutrition
- if you have cardiovascular disease (heart or circulatory disease)
- if you are at increased risk of cardiovascular disease. Risk factors include being aged over 35 years and a cigarette smoker or having high blood pressure, high blood cholesterol levels or diabetes
- if you have an illness that affects the clotting of your blood
- if you have had a previous caesarean section or surgery of the womb.

Health care professionals should ensure that due to the risk of the failure of the method and the birth defects observed in these ongoing pregnancies, patients are being informed about the risk of teratogenicity and that a

follow-up visit must be scheduled in order to check that the expulsion is completed (see section Pregnancy, breast-feeding and fertility).

Before taking mifepristone and MisoOne your blood will be tested for Rhesus factor. If you are Rhesus negative your doctor will advise you of the routine treatment required.

For medical termination of pregnancy:

If you use a contraceptive coil, it must be removed before you take the first medicine, mifepristone.

For surgical termination of pregnancy:

- As no data are available on cervical preparation with misoprostol prior to surgical termination of pregnancy beyond the first trimester, MisoOne is not taken beyond 12 weeks after the first day of your menstruation.
- Due to possible occurrence of vaginal bleeding after taking this medicine, you should preferably take MisoOne at the treatment centre before the surgical procedure.

Other medicines and MisoOne

Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

In particular tell your doctor if you are taking any of the following

- Non-steroidal anti-inflammatory drugs (NSAIDs) such as acetylsalicylic acid or diclofenac
- Antacid medicines or an antacid medicine containing magnesium (used to treat heartburn and acid indigestion)

Pregnancy, breast-feeding and fertility

Pregnancy

Failure of pregnancy termination (continuing pregnancy) after taking MisoOne has been associated with a 3-fold increased risk of birth defects, in particular facial paralysis, head and limb malformations. Defects in newborns have also been seen when this medicine is taken on its own. For medical termination of pregnancy, you **must** take the other medicine, mifepristone, 36 – 48 hours before taking MisoOne.

The risk of failure of MisoOne increases

- If it is not taken orally
- With the duration of the pregnancy
- With the number of pregnancies you have had before
- For medical termination of pregnancy, if it is taken later than 49 days after the first day of your last menstrual period

If termination of the pregnancy fails after taking this medicine, there is an unknown risk to the foetus. If you decide to continue with the pregnancy, careful pre-natal monitoring and repeated ultrasound examinations, with a special attention to the limbs and head, in a specialised clinic must be carried out. Your doctor will advise further.

If you decide to continue with the termination of the pregnancy a new procedure will be used. Your doctor will advise you of the options.

You should avoid getting pregnant again before your next period after taking this medicine. You should start contraception immediately after the termination of the pregnancy is confirmed by the doctor.

Breast-feeding

If you are breast-feeding, ask your doctor for advice before taking this medicine. Do not breast-feed as this medicine is passed into breast milk.

Fertility

This medicine does not affect fertility. You can become pregnant again as soon as your termination is completed. You should start contraception immediately after the termination of the pregnancy is confirmed.

Driving and using machines

This medicine can cause dizziness. Take special care when driving or using machines after taking this medicine until you know how MisoOne affects you.

3. How to take MisoOne

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

Dosage in Adults

- One tablet to be taken orally.

Taking the Tablet

- **In all instances:**
 - Swallow the tablet whole with a glass of water,
 - If you vomit within 30 minutes of taking the tablet, talk to your doctor immediately. You will need to take another tablet.

Contact your prescribing centre immediately after the termination of pregnancy procedure (medical or surgical):

- **if you have vaginal bleeding for longer than 12 days and/or if it is very heavy (e.g. you need more than 2 sanitary pads per hour for 2 hours)**
- **if you have severe abdominal pain**
- **if you have a fever or if you are feeling cold and shivering.**
- **For medical termination of pregnancy**

The schedule for taking MisoOne for a medical termination of pregnancy will be as follows.

- 1) At the prescribing centre you will be given the first drug mifepristone, which must be taken orally.
- 2) 36 – 48 hours after this, you will take MisoOne orally. You must rest for at least 3 hours after taking this medicine.
- 3) The embryo may be expelled within a few hours of taking MisoOne or during the next few days. You will have vaginal bleeding which will last for an average of 12 days after taking the first drug, mifepristone, and the flow will become lighter as time continues.
- 4) **You must return to the centre within 14 - 21 days of taking the first medicine, mifepristone, for a check-up consultation to make sure the expulsion is complete.**

Important things to remember when taking this medicine:

This tablet must be taken orally

For medical termination of pregnancy, MisoOne must be taken 36 – 48 hours after taking 600 mg of mifepristone

If you do not follow these instructions the risks associated with this medicine will increase

- **For surgical termination of pregnancy**

The tablet is to be taken 3 to 4 hours before the surgical procedure of termination of pregnancy.

The schedule for taking MisoOne for a surgical termination of pregnancy will be as follows.

- 1) Take MisoOne orally
- 2) Surgical procedure will be conducted 3 to 4 hours after this intake

You will have vaginal bleeding which will last for an average of 12 days after the surgical procedure, and the flow will become lighter as time continues.

3) You must return to the centre within 14 - 21 days after this surgical procedure, for a check-up consultation.

Other important points to remember:

- In all instances
 - Do not take this medicine if the blister foil is damaged or if the tablet has been stored outside the packaging.

In case of emergency or if you have any questions, telephone or visit your prescribing centre. You do not have to wait for your check-up appointment.

- For medical termination of pregnancy
 - Vaginal bleeding does not mean the expulsion has been completed after a termination of pregnancy.
 - The risk of side effects increases if you do take this medicine later than 49 days after the first day of your last menstrual period or if you do not take it orally.

If pregnancy continues or expulsion is incomplete, your doctor will advise you of the options for termination of the pregnancy.

It is recommended that you do not travel too far away from the prescribing centre until the check-up consultation is done.

- For surgical termination of pregnancy
 - After taking MisoOne, there is a risk of abortion before surgical procedure has started even though this risk is low.
 - The risk of side effects increases if you take it later than 12 weeks after the first day of your last menstrual period (first trimester of pregnancy).

Use in children and adolescents

Only limited data is available on the use of misoprostol in adolescents.

If you take more MisoOne than you should

If you take too many tablets, contact your doctor immediately or go to the nearest hospital casualty department.

The doctor will give you the exact amount of MisoOne ; it is therefore unlikely that you will take too many tablets. Taking too many tablets may cause symptoms such as drowsiness, shaking, fits, difficulty in breathing, abdominal pain, diarrhoea, fever, chest pain, low blood pressure and a slow heartbeat that can be fatal.

If you forget to take MisoOne

If you forget to take mifepristone or MisoOne it is likely that the termination will not be fully effective. Talk to your doctor or the prescribing centre if you forget to take MisoOne .

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

The following side effects may occur:

Serious Side Effects

The risk of serious side effects increases if you take this medicine later than:

- 49 days after the first day of your last menstrual period for a medical termination of pregnancy.

Or

- 12 weeks after the first day of your last menstrual period for a surgical termination of pregnancy.

Serious side effects include:

- allergic reaction. Severe skin rashes such as itchy red spots, blisters or lesions.
- cardiovascular accidents. Chest pain, difficulty breathing, confusion, or an irregular heartbeat. This may lead to cardiac arrest

Other serious side effects include:

- cases of serious or fatal toxic or septic shock. Fever with aching muscles, rapid heart rate, dizziness, diarrhoea, vomiting or feeling weak. These side effects may occur if you do not take this medicine orally or if you take it later than 49 days after the first day of your last menstrual period for a medical termination of pregnancy.

If you experience any of these side effects, contact your doctor IMMEDIATELY or go to your nearest hospital casualty department.

Other side effects

Very common (may affect more than 1 in 10 people):

- uterine contractions or cramping
- diarrhoea
- feeling sick (nausea) or being sick (vomiting)
- uterine bleeding

Common (may affect up to 1 in 10 people):

- heavy vaginal bleeding
- abdominal pain
- gastro-intestinal cramping light or moderate
- infection of the uterus (endometritis and pelvic inflammatory disease)
- birth defects (foetal malformations)

Rare (may affect up to 1 in 1,000 people):

- fever
- foetal death
- headache, dizziness and generally feeling unwell or tired
- hives and skin disorders which can be serious
- tearing of the womb (uterine rupture): tearing of the womb after administration of prostaglandins in the second or third trimester of pregnancy, mainly in women with previous deliveries of a child or with a scar of a caesarian section.

Very rare (may affect up to 1 in 10,000 people):

- localised swelling of face and/or larynx which can be with urticaria

Other side effects include:

- feeling cold, shivering
- back pain

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet.

You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store MisoOne

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 carton after “EXP.”. The expiry date refers to the last day of that month.

Store below 25°C.

Do not use this medicine if you notice that the box or the blister packs show signs of damage.

Do not use if the tablet has been stored outside the blister pack.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What MisoOne contains

The active substance is misoprostol.

One tablet MisoOne contains 400 microgram misoprostol.

The other ingredients are microcrystalline cellulose, hypromellose, sodium starch glycolate (type A), hydrogenated castor oil.

What MisoOne looks like and contents of the pack

White, round, flat tablet with a diameter of 11 mm and thickness of 4.5 mm, with a break line on each side and double “M” engraved on one side. The tablet can be divided into equal doses.

MisoOne is available in pack sizes of 1, 4, 16 or 40 tablets in perforated unit dose PVC-PCTFE/Alu or Alu/Alu blisters.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder

EXELGYN

216 boulevard Saint-Germain

75007 Paris

France

Manufacturer

Nordic Pharma B.V.

Siriusdreef 41

2132 WT Hoofddorp

The Netherlands

Delpharm Lille SAS

Parc D'Activitiés Roubaix Est

22 Rue de Toufflers, Cs 50070

59452 Lys-Lez-Lannoy Cedex

France

Laboratoires MACORS
22 Rue des Caillottes
89000 Auxerre
France

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: Topogyne
Belgium: Topogyne
Bulgaria: Topogyne
Croatia: Mispregmol
Cyprus: MisoOne
Czech Republic: Mispregmol
Denmark: Topogyne
Estonia: Topogyne
Finland: Topogyne
France: MisoOne
Germany: MisoOne
Greece: MisoOne
Ireland: MisoOne
Italy: Misoone
Latvia: Misoone
Luxembourg: Topogyne
Norway: Topogyne
Portugal: Topogyne
Romania: Topogyne
Slovenia: Topogyne
Spain: MisoOne
Sweden: Topogyne
The Netherlands: MisoOne
UK (Northern Ireland): Topogyne

This leaflet was last revised in