

## **Package leaflet: Information for the user**

### **Medabon Combipack of Mifepristone 200 mg tablet and Misoprostol 4 x 0.2 mg vaginal tablets Mifepristone and 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 pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **In this leaflet**

1. What Medabon is and what it is used for
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#### **1. What Medabon is and what it is used for**

Medabon is a combination therapy containing two medicines called mifepristone and misoprostol.

Medabon is recommended for the medical termination of a pregnancy no later than 63 days after the first day of your last menstrual period.

Mifepristone is an anti-hormone that acts by blocking the effects of progesterone, a hormone which is needed for pregnancy to continue. Misoprostol is a prostaglandin, which is a substance that increases contraction of the womb that will help expel the pregnancy. The two drugs can therefore cause termination of pregnancy and must be used one after the other to give the best possible chance for the treatment to work.

#### **2. What you need to know before you use Medabon**

##### **Do not use Medabon**

- if your pregnancy has not been confirmed by gynecological examination, ultrasound scan or biological tests
- if the first day of your last period was more than 63 days ago (if there is any doubt, the doctor can check the age of your pregnancy with a scanner)
- if your doctor suspects an extra-uterine pregnancy (the egg is implanted outside the womb)
- if you are allergic to mifepristone, misoprostol (or any other prostaglandins) or any of the other ingredients of this medicine (listed in section 6)

- if you suffer from severe asthma which cannot be adequately treated with medication
- if you have hereditary porphyria (an inherited disorder of the blood)
- if you suffer from chronic adrenal failure.

### **Warnings and precautions**

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 2. 'Pregnancy, breast-feeding and fertility').

Serious skin reactions including toxic epidermal necrolysis and acute generalized exanthematous pustulosis have been reported in association with mifepristone treatment. Seek medical attention immediately if you notice any of the symptoms described in section 4. If you get a serious skin reaction you should not use mifepristone again in the future.

### **In some circumstances the treatment may not be suitable for you or you may need extra care, so please tell your doctor if**

- if you have undergone genital cutting or circumcision
- if you cannot easily get emergency medical help in the 2 weeks after you use Medabon
- you have a heart complaint
- your heart has been fitted with an artificial valve
- you have a risk factors for heart diseases, such as high blood pressure or high blood cholesterol levels (increased fat content in your blood)
- you suffer from asthma
- you suffer from an illness that may affect the clotting of your blood
- you have liver or kidney disease
- you are anaemic or otherwise malnourished.

Before taking Medabon your blood will be tested for Rhesus factor. If you are Rhesus negative your doctor will advise you of the routine treatment required (see also in section 3. 'After treatment you should be aware that').

The doctor will then be able to discuss with you if you are able to have the treatment.

### **Other medicines and Medabon**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, medicines containing the following active substances may interfere with the action of Medabon:

- corticosteroids, such as dexamethasone (used to treat asthma or inflammation)
- ketoconazole, itraconazole (used in antifungal treatment)
- erythromycin, rifampicin (antibiotics)
- St John's Wort (natural remedy used to treat mild depression)
- phenytoin, phenobarbital, carbamazepine (used to treat seizures or epilepsy).

Caution should be exercised when Medabon is used with medicines containing the following active substances:

- immunospressants such as cyclosporine, tacrolimus, sirolimus, everolimus (used to prevent the body from rejecting a transplanted organ)
- alfentanil, fentanyl (used to relieve pain)
- ergotamine, diergotamine (used to treat migraines)
- quinidine (used to help keep the heart beating normally)
- some agents used during general anesthesia.

The incidence of diarrhea may be reduced by avoiding antacids that contain magnesium. If an antacid is needed, one that contains aluminum or calcium may be a more appropriate choice.

Ask your doctor about which medicines you can take for pain.

Talk to your doctor if you need to take any other medicines during the treatment.

### **Medabon with food and drink**

You should not drink grapefruit juice when you are treated with Medabon.

### **Pregnancy, breast-feeding and fertility**

#### Pregnancy

There is little information on the risks to the unborn baby. Failure of pregnancy termination (continuing pregnancy) after taking Medabon after the first medicine (mifepristone) has been associated with a 3-fold increased risk of birth defects, in particular facial paralysis, head and limb malformations. If you decide to continue with the, careful pre-natal monitoring and ultrasound examinations, with a special attention to the limbs and head, in a specialised clinic must be carried out.

#### Breast-feeding

Medabon may pass into breast milk and be taken in by your baby. You should stop breast-feeding once you have used the treatment.

#### Fertility

**Important:** It is possible for you to become pregnant again very soon after the pregnancy termination is complete. It is recommended that you avoid becoming pregnant again before your next menstrual period after taking Medabon, and use a method of contraception within 3 to 9 days of using the mifepristone tablet (see also in section 3. 'After treatment you should be aware that').

### **Driving and using machines**

You should know that mifepristone and misoprostol may make you dizzy. Do not drive a car or operate machinery until you know how this medication affects you.

## **3. How to use Medabon**

- For pregnancies that have occurred with an intrauterine contraceptive device (coil) in place, this must be removed prior to administering Medabon.
- It is recommended that you do not travel too far away from the prescribing hospital/clinic until the follow-up (see 'Third step below'), in case in an emergency you need to return to the hospital/clinic. In an emergency or if you are worried for any reason, you can contact or return to the hospital/clinic before the appointment time. You will be given the telephone number to call for emergencies or any problems.

The use of Medabon requires your active participation as follows:

#### **First step**

- Take one tablet of mifepristone 200 mg to swallow with some water.
- If you vomit shortly after administration of mifepristone, please inform the doctor.
- If you experience symptoms such as severe abdominal pain, fainting, fast heartbeat, fever lasting more than 4 hours after taking the tablet, please tell your doctor.

- In rare cases, the pregnancy may be expelled before you use the misoprostol tablets. It is essential that you still have a follow-up consultation to confirm that a complete pregnancy termination has occurred (see 'Third step' below).

### **Second step**

- 36 to 48 hours after taking mifepristone, the four misoprostol vaginal tablets are inserted into the vagina.
- If you receive misoprostol in a clinic, you may be asked to stay for 3 hours after the misoprostol vaginal tablets are inserted or until you feel comfortable and able to return home.
- If you use the misoprostol vaginal tablets at home, follow the same insertion instructions as given above. Please make sure that you empty your bladder and clean your hands thoroughly before inserting the misoprostol vaginal tablets. Push the four vaginal tablets one at a time up into the vagina as far as you can using your finger.
- After the misoprostol vaginal tablets have been inserted into the vagina, remain lying down for 30 minutes.
- The pregnancy may be expelled within a few hours or during the next few days after misoprostol treatment.

### **Third step**

- To confirm you are no longer pregnant, a follow-up is required 14 – 21 days after the mifepristone tablet was swallowed.
- A special type of pregnancy test after about 2 weeks is required, to confirm the pregnancy has ended. Some women may need to have a scan to confirm the pregnancy has ended.
- A follow up consultation can take place remotely by phone, video call, text messaging or other form of communication with your healthcare professional.
- It is important that you keep this follow-up appointment to check that your pregnancy has been completely expelled and you are well.

### **After treatment you should be aware that**

- Uterine bleeding usually starts 1 to 2 days after taking the mifepristone tablet. The bleeding lasts 2 or 3 weeks (on average 13 days). If the bleeding is heavy and prolonged, contact the doctor immediately.
- The presence of these bleedings is not related to the success of the method. If pregnancy continues or expulsion is incomplete, you will be offered a surgical method for terminating the pregnancy.
- If the pregnancy continues and you decide to keep it, discuss this with your doctor who will arrange careful pre-natal monitoring and ultrasound examinations.
- **Important:** It is possible for you to become pregnant again very soon after the pregnancy termination is complete. It is recommended that you avoid getting pregnant again soon after the termination. You should therefore start using a method of contraception within 3 to 9 days of taking the mifepristone tablet. Discuss contraceptive options with your doctor.

The use of Medabon requires that measures are taken to prevent Rhesus factor sensitisation (*if you are Rhesus negative*) along with the general measures taken during any pregnancy termination.

### **If you use more Medabon than you should**

The doctor will give you the exact amount of Medabon; it is therefore unlikely that you will use more than you should.

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

In the event of accidental massive ingestion, contact your doctor immediately or go to the nearest hospital casualty department. You may require specialist treatment including the administration of dexamethasone.

#### **If you forget to use Medabon**

If you forget to use any part of the treatment, it may not be fully effective. This means that your pregnancy may not have been completely expelled. Talk with your doctor if you forgot to use any part of the treatment, as you may need further treatment to end the pregnancy. Also if you change your mind and choose to continue with your pregnancy, talk to your doctor (see also section 2. Pregnancy, breast-feeding and fertility; Pregnancy).

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

#### **4. Possible side effects**

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

##### **Serious side effects**

##### **Contact the hospital/clinic if you have:**

- 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
- persistent heavy bleeding, for example soaking two sanitary pads per hour, for more than two hours
- persistent fever with a temperature of 38°C or higher, for more than four hours
- reddish patches on the trunk, the patches are target-like macules or circular, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (toxic epidermal necrolysis, frequency: rare or very rare)
- a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis, frequency: not known)
- an unpleasant smelling discharge
- persistent pain unrelieved by medication.

##### **Contact your doctor if any of the following side effects gets serious or you are worried.**

##### **Very common side effects (may affect more than 1 in 10 people)**

- uterine contractions or lower abdominal cramps in the hours following misoprostol.

##### **Common side effects (may affect up to 1 in 10 people)**

- birth defects (foetal malformations)
- heavy bleeding
- gastrointestinal cramping, light or moderate
- nausea, vomiting or diarrhoea. These side effects are related to misoprostol use.

##### **Uncommon side effects (may affect up to 1 in 100 people)**

- infection following abortion

- hypersensitivity: skin rashes.

**Rare side effects (may affect up to 1 in 1,000 people)**

- headaches
- malaise (feeling unwell)
- hot flushes, dizziness, chills
- fever
- low blood pressure
- hives and skin disorders, which can be serious
- uterine rupture.

**Very rare side effects (may affect up to 1 in 10,000 people)**

- fatal toxic shock caused by infection by *Clostridium sordellii* endometritis, presenting without fever or other obvious symptoms of infection.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Medabon**

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if the box or the blisters show signs of damage.

Store below 25°C.

**6. Contents of the pack and other information**

**What Medabon contains**

Each tablet of mifepristone contains 200 mg mifepristone.

Each vaginal tablet of misoprostol contains 0.2 mg misoprostol.

The other ingredients are:

- mifepristone tablet; silica, colloidal anhydrous, maize starch, microcrystalline cellulose (E460), povidone K30, and magnesium stearate (E470b).
- misoprostol vaginal tablet; hypromellose (E464), microcrystalline cellulose (E460), sodium starch glycolate (type A), and castor oil, hydrogenated.

**What Medabon looks like and contents of the pack**

Medabon contains 1 tablet of mifepristone and 4 vaginal tablets of misoprostol supplied in an aluminium blister. Each blister is packed in an aluminium pouch along with a silica gel desiccant sachet.

Mifepristone tablet is light yellow coloured and round-shaped, one side is marked with “S” and the other side is plain. Diameter: 11.0 mm.

Misoprostol vaginal tablets are white to off-white and rectangular-shaped, one side is marked with a square on each side of the score and the other side is plain. Diameter: 11.6 x 6.3 mm.

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

The Netherlands: Sunmedabon  
Romania: Medabon  
United Kingdom: Medabon

**This leaflet was last revised in August 2021.**