044BP1361B

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

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.

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

2. What you need to know before you take Medabon

- **Do not take 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 have undergone genital cutting or circumcision,
- if you cannot return for a follow up visit to assess that the pregnancy is completely terminated (see section 3),
- if you cannot easily get emergency medical help in the 2 weeks after you take Medabon,
- if you are allergic to mifepristone, misoprostol (or any other prostaglandins) or any of the other ingredients of this medicine (listed in section6),
- 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

In some circumstances the treatment may not be suitable for you, so please tell your doctor if:
- 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.

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 (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).

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 and breast feeding
Medabon may pass into breast milk and be taken in by your baby. You should stop breast feeding once you have taken the treatment.
There is little information on the risks to the unborn baby. 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.
It is recommended that you avoid becoming pregnant again before your next menstrual period after taking Medabon.

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 take Medabon

- For pregnancies that have occurred with an intrautrine 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 visit date. 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 visit to the hospital/clinic
- You will be given one tablet of mifepristone 200 mg to swallow with some water in the presence of a doctor or a member of his/her medical staff.
- You will be able to go home after taking the tablet of mifepristone once the doctor is sure that you will not be sick. 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 take the misoprostol tablets. It is essential that you return to the hospital/clinic to confirm that a complete pregnancy termination has occurred.

Follow-up visit
- You must return to the hospital/clinic 36 to 48 hours after taking mifepristone.
- You will be given 4 vaginal tablets of misoprostol to ensure the treatment is effective. The doctor or nurse will place the tablets into your vagina or you may do this yourself. In this case, 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. It is recommended that you lie down for about 30 minutes after the misoprostol vaginal tablets have been inserted.
- You should stay in the hospital/clinic for a few hours or until you and the doctor are happy that you are well enough to go home. The pregnancy may be expelled within a few hours or during the next few days after misoprostol treatment.

Third visit
- You must return to the hospital/clinic for a check up within 14 – 21 days of taking the mifepristone tablet.
- It is important that you keep this appointment to check that your pregnancy has been completely expelled and you are well, as you will not be able to judge for yourself if the treatment has been successful.

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 for an earlier appointment.
- 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 take more Medabon than you should
As you will be supervised during administration of the treatment, it is unlikely that you will take more than you should.

If you forget to take Medabon
If you forget to take any part of the treatment, it may not be fully effective. Talk with your doctor if you forgot to take the treatment.

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

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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:
- 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
- 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)
- heavy bleeding
- gastrointestinal cramping, light or moderate
- nausea, vomiting or diarrhoea.

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.

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

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.
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.

Marketing Authorisation Holder and Manufacturer
Sun Pharmaceutical Industries Europe B.V.
Polarisavenue 87
2132 JH Hoofddorp
The Netherlands

Do not Print in Grey area

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

Bulgaria:	МЕДАБОН
Czech Republic:	Sunmedabon
Denmark:	Medabon
Estonia:	Medabon
Finland:	Medabon
Hungary:	Sunmedabon
Iceland:	Medabon
Latvia:	Medabon
The Netherlands:	Sunmedabon
Norway:	Sunmedabon
Romania:	Medabon
Sweden:	Medabon
Slovakia:	Mifepristón SUN 200 mg tableta Misoprostol SUN 4 x 0,2 mg vaginálne tablety
United Kingdom:	Medabon

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