

SCHEDULING STATUS: **S4**

ACEGYNE

Mifepristone 200 mg tablets

Sugar free

Read all of this leaflet carefully before you start taking ACEGYNE

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- ACEGYNE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

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

1. What ACEGYNE is and what it is used for

ACEGYNE tablets contain mifepristone which is an anti-hormone that acts by blocking the effects of progesterone, a hormone which is needed for pregnancy to continue. ACEGYNE can therefore cause termination of pregnancy. It can also be used to soften and open the entrance (the cervix) to the womb (uterus).

ACEGYNE is recommended to be used:

1) For the medical termination of a pregnancy:

- no later than 56 days after the first day of your last menstrual cycle,

- in combination with a second medicine, a prostaglandin (a substance that triggers contraction of the womb and softens the cervix), which you take 36 to 48 hours after taking ACEGYNE.

2) For softening and opening of the cervix before surgical termination of pregnancy during the first trimester.

3) As pre-treatment before giving prostaglandins for termination of pregnancy for medical reasons beyond 3 months gestation.

4) To induce labour in cases where the foetus has died in the womb and where it is not possible to use other medical treatments (prostaglandin or oxytocin).

2. What you need to know before you take ACEGYNE

Do not take ACEGYNE

• In all cases,

- if you are allergic to mifepristone or any of the other ingredients of this medicine (listed in section 6),
- if you suffer from kidney failure,
- 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 have an unremoved intra-uterine contraceptive device,
- if pregnancy is not confirmed by ultrasound scan or biological tests,
- if your doctor suspects an ectopic pregnancy.
- If you are on long-term corticosteroid (used in the treatment of asthma or other inflammation treatments) treatment,
- If you suffer from haemorrhagic disorders (illness that affects clotting of your blood) or taking anticoagulants (medicines that help prevent blood clots).

Warnings and precautions

Talk to your doctor before taking ACEGYNE:

- 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 suffer from asthma.

If you use a contraceptive coil, it must be removed before you take ACEGYNE.

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

It is essential that you attend a follow-up visit with your doctor 10 – 14 days after taking ACEGYNE to ensure that the pregnancy has been successfully terminated. If pregnancy continues or expulsion is incomplete, your doctor will advise you of the options for completion of the pregnancy termination.

Other medicines and ACEGYNE

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

In particular tell your doctor if you are taking the following:

- corticosteroids (used in the treatment of asthma or other inflammation treatments)
- ketoconazole, itraconazole (used in antifungal treatment)
- erythromycin, rifampicin (antibiotics)
- St John's Wort (natural remedy used in the treatment of mild depression)
- phenytoin, phenobarbital, carbamazepine (used in the treatment of seizures, epilepsy)
- non-steroidal anti-inflammatory drugs (NSAIDs) such as acetyl salicylic acid or diclofenac.

ACEGYNE with food and drink

Grapefruit juice should not be taken when you are treated with ACEGYNE.

Pregnancy, breast-feeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using ACEGYNE

Pregnancy

ACEGYNE is indicated for the termination of pregnancy and has no other use during pregnancy.

Breastfeeding

If you are breastfeeding, talk to your doctor before using this medicine. Do not breastfeed while taking ACEGYNE.

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 by your doctor.

Driving and using machines

Dizziness can occur as a side effect related to the abortion process. Take special care when driving or using machines after taking this medicine until you know how ACEGYNE affects you.

3. How to take ACEGYNE

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

1) Medical alternative to surgical termination of intrauterine pregnancy

Dosage in adults

- 3 tablets to be taken orally

Taking the tablet

- Swallow the tablets whole with a glass of water in the presence of a doctor or a member of his/her medical staff
- Take the prostaglandin analogue, 36 – 48 hours after ACEGYNE. The prostaglandin is given as tablets which should be swallowed with water (misoprostol 400 micrograms)
- If you vomit within 45 minutes after taking the mifepristone tablets, talk to your doctor immediately. You will need to take the tablets again.

2) For softening and opening the cervix before surgical termination of pregnancy:

Dosage in adults

- 3 tablets to be taken orally

Taking the tablet

- Swallow the tablet whole with a glass of water
- If you vomit within 45 minutes after taking the mifepristone tablet, talk to your doctor immediately. You will need to take another tablet.

The schedule for the medical termination of pregnancy will be as follows:

- 1) At the prescribing centre you will be given ACEGYNE, which must be taken orally
- 2) 36 to 48 hours after this you will come back to the prescribing centre for the surgical procedure.

Your doctor will explain the procedure to you. It is possible that you will experience bleeding after taking ACEGYNE, before the surgery.

In rare cases, expulsion can also occur before surgery. It is essential that you return to the centre to confirm that a complete evacuation has occurred.

You must return to the centre selected for the surgery.

In case of emergency or if you have any questions, telephone or visit your prescribing centre.

You do not have to wait for your follow-up appointment.

3) For termination of pregnancy beyond first three months of pregnancy:

Dosage in adults

- 3 tablets to be taken orally

Taking the tablet

- Swallow the tablets whole with a glass of water
- 36 – 48 hours after this medicine take the prostaglandin analogue, which may be repeated several times at regular intervals until the termination is complete.
- If you vomit within 45 minutes after taking the mifepristone tablets, talk to your doctor
- immediately. You will need to take the tablets again.

4) For inducing labour when pregnancy has been interrupted (intra-uterine foetal death).

Dosage in adults

- 3 tablets to be taken orally each day for two days

Taking the tablet

- Swallow the tablets whole with a glass of water
- If you vomit within 45 minutes after taking the mifepristone tablets, talk to your doctor immediately. You will need to take the tablets again.

If you take more ACEGYNE than you should

The doctor will give you the exact amount of ACEGYNE; it is therefore unlikely that you will take too many tablets. Taking too many tablets may cause symptoms of adrenal failure. Signs of acute intoxication may require specialist treatment including the administration of dexamethasone.

If you forget to take ACEGYNE

If you forget to take any part of the treatment, it is likely that the method will not be fully effective. Talk with your doctor if you forgot to take ACEGYNE or the part of treatment prescribed.

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

4. Possible side effects

ACEGYNE can have side effects.

Not all side effects reported for ACEGYNE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ACEGYNE, please consult your health care provider for advice.

If any of the following happens, stop using ACEGYNE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reaction. Skin rash, localised swelling of face and/or larynx which can be with urticaria

These are all very serious side effects. If you have them, you may have had a serious reaction to ACEGYNE. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Cases of serious or fatal toxic or septic shock.

- Fever with aching muscles, rapid heart rate, dizziness, diarrhoea, vomiting or feeling week. This side effect may occur if you do not take the second medicine, the misoprostol tablet, orally.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following side effects:

Frequent:

- dizziness
- uterine contractions or cramping
- diarrhoea
- feeling sick (nausea), or being sick (vomiting)
- heavy bleeding,
- gastrointestinal cramping light or moderate
- infection of the uterus (endometritis and pelvic inflammatory disease)

Less Frequent:

- blood pressure fall
- fever, headache
- Uterine rupture following prostaglandin administration within the second and third trimester of pregnancy, particularly in multiparous women or in women with a caesarean section scar

Frequency unknown:

- generally feeling unwell or tired
- vagal symptoms (hot flushes, dizziness, chills)
- hives, swelling under the skin, blistering and peeling of the skin and skin disorders which can be serious

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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 to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of ACEGYNE

5. How to store ACEGYNE

Store at or below 25^o C

Store in the original package

KEEP OUT OF REACH OF CHILDREN

6. Contents of the pack and other information

What ACEGYNE contains

The active substance is mifepristone

The other ingredients are:

Microcrystalline cellulose

Maize starch

Povidone (K30)

Sodium lauryl sulphate

Croscarmellose sodium

Colloidal silicon dioxide

Magnesium stearate

What ACEGYNE looks like and contents of the pack

Light yellow coloured, round shaped, uncoated tablets with break line on one side and plain on the other side

Tablets are packed in in blister pack comprising of transparent PVC/PVDC film backed by ALU foil in cartons of 1, 3, 6, 15 or 30 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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