PACKAGE LEAFLET

Package leaflet: Information for the user

Ulipristal Acetate Rowex 30 mg film-coated tablets

ulipristal acetate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet
1. What Ulipristal Acetate Rowex is and what it is used for
2. What you need to know before you take Ulipristal Acetate Rowex
3. How to take Ulipristal Acetate Rowex
4. Possible side effects
5. How to store Ulipristal Acetate Rowex
6. Contents of the pack and other information
   - Useful information about contraception

1. What Ulipristal Acetate Rowex is and what it is used for

Ulipristal Acetate Rowex is an emergency contraceptive
Ulipristal Acetate Rowex is a contraceptive intended to prevent pregnancy after unprotected sex or if your contraceptive method has failed. For example:
- if you had sex without protection
- if your or your partner's condom tore, slipped or came off, or if you forgot to use one
- if you did not take your contraceptive pill as recommended.

You should take the tablet as soon as possible after sex, and within a maximum of 5 days (120 hours). This is because the sperm can survive up to 5 days in your body after intercourse.

This medicine is suitable for any woman of childbearing age, including adolescents.

You can take the tablet at any time in the menstrual cycle.

Ulipristal Acetate Rowex does not work if you are already pregnant
If your menstrual period is late, there is a possibility that you may be pregnant. When your period is late or when you have symptoms of pregnancy (heavy breasts, morning sickness) you should consult a doctor or other healthcare professional before taking the tablet.

If you have unprotected sex after taking the tablet, it will not stop you from becoming pregnant. Unprotected sex at any time during your cycle can lead to pregnancy.

Ulipristal Acetate Rowex is not to be used for regular contraception
If you do not have a regular method of contraception, talk to your doctor or healthcare professional to choose one that is suitable for you.

How Ulipristal Acetate Rowex works
Ulipristal Acetate Rowex contains the substance ulipristal acetate which acts by modifying the activity of the natural hormone progesterone which is necessary for ovulation to occur. As a result, this medicine works by postponing ovulation. Emergency contraception is not effective in every case. Of 100 women who take this medicine approximately 2 will become pregnant.

This medicine is a contraceptive used to prevent a pregnancy from starting. If you are already pregnant, it will not interrupt an existing pregnancy.

Emergency contraception does not protect against sexually transmitted infections
Only condoms can protect you from sexually transmitted infections. This medicine will not protect you against HIV infection or any other sexually transmitted diseases (e.g. chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B and syphilis). Ask a healthcare professional for advice if you are worried about this.

There is more information about contraception at the end of this leaflet.

2. What you need to know before you take Ulipristal Acetate Rowex

Do not take Ulipristal Acetate Rowex
- if you are allergic to ulipristal acetate or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your pharmacist, doctor or other healthcare professional before taking this medicine.
- if your period is late or you have symptoms of pregnancy (heavy breasts, morning sickness), as you may already be pregnant (see section "Pregnancy, breast-feeding and fertility*")*
- if you suffer from severe asthma
- if you suffer from severe liver disease.

In all women, emergency contraception should be taken as soon as possible after unprotected intercourse. There is some evidence that this medicine may be less effective with increasing body weight or body mass index (BMI), but these data were limited and inconclusive. Therefore, ulipristal acetate is still recommended for all women regardless of their weight or BMI.

You are advised to speak to a healthcare professional if you are concerned about any problems related to taking emergency contraception.

If you become pregnant despite taking this medicine, it is important that you see your doctor. See section "Pregnancy, breast-feeding and fertility" for more information.

Other contraceptives and Ulipristal Acetate Rowex
This medicine may make regular hormonal contraceptives, like pills and patches, temporarily less effective. If you are currently taking hormonal contraception, continue to use it as usual after taking this medicine, but be sure to use condoms every time you have sex until your next period.

Do not take this medicine together with another emergency contraceptive pill that contains levonorgestrel. By taking them both together, you might make this medicine less effective.

Other medicines and Ulipristal Acetate Rowex
Tell your pharmacist, doctor or other healthcare professional if you are taking/using, have recently taken/used or might take/use any other medicines, including medicines obtained without prescription or herbal medicines.

Some medicines may prevent Ulipristal Acetate Rowex from working effectively. If you have used any of the medicines listed below during the last 4 weeks, Ulipristal Acetate Rowex may be less suitable for you. Your doctor may prescribe another type of (non-hormonal) emergency contraceptive, i.e. a copper intrauterine device (Cu-IUD):

- medicines used to treat epilepsy (for example, primidone, phenobarbital, phenytoin, fosphenytoin, carbamazepine, oxcarbazepine and barbiturates)
- medicines used to treat tuberculosis (for example, rifampicin, rifabutin)
- a treatment for HIV (ritonavir, efavirenz, nevirapine)
- a medicine used to treat fungal infections (griseofulvin)
- herbal remedies containing St John's wort (Hypericum perforatum).

Speak to your doctor or pharmacist before using Ulipristal Acetate Rowex when you use (or have recently used) any of the medicines stated above.

Pregnancy, breast-feeding and fertility
Pregnancy
Before taking this medicine, if your period is late, tell your pharmacist, doctor or other healthcare professional, or do a pregnancy test in order to make sure you are not already pregnant (see section *"*Warning and precautions").

This medicine is a contraceptive used to prevent a pregnancy from starting. If you are already pregnant it will not interrupt an existing pregnancy.

If you become pregnant despite taking this medicine, there is no evidence that it will affect your pregnancy. However, it is important that you see your doctor. As for any pregnancy, your doctor may want to check that the pregnancy is not outside the womb. This is especially important if you have severe abdominal (stomach) pain or bleeding or if you have previously had a pregnancy outside the womb, tubal surgery or long term (chronic) genital infection.

If you become pregnant despite taking Ulipristal Acetate Rowex, you are encouraged to ask your doctor to register your pregnancy in an official registry. You can also report this information on your own at www.ulipristal-pregnancy-registry.com. Your information will remain anonymous – nobody

will know it is information about you. Sharing your information may help women in the future understand the safety or risks of Ulipristal Acetate Rowex during a pregnancy.

Breast-feeding
If you take this medicine while you are breast-feeding a baby, do not breast-feed for one week after taking this medicine. During this time, it is recommended to use a breast pump in order to maintain milk production, but throw away your breast milk. The effect of breast-feeding your baby in the week after taking this medicine is not known.

Fertility
This medicine will not affect your future fertility. If you have unprotected sex after taking this medicine, it will not stop you from becoming pregnant. Therefore it is important you use condoms until your next period.
If you wish to start or continue with a regular method of contraception after using this medicine, you can do so but you should also use condoms until your next period.

Driving and using machines
After taking this medicine, some women experience dizziness, drowsiness, blurred vision and/or loss of concentration (see section 4). If you experience these symptoms, do not drive or use machines.

Ulipristal Acetate Rowex contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
Ulipristal Acetate Rowex contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially “sodium-free”.

3. How to take Ulipristal Acetate Rowex

Always take this medicine exactly as described in this leaflet or as your pharmacist, doctor or other healthcare professional has told you. Check with your pharmacist or doctor if you are not sure.

How to take the Ulipristal Acetate Rowex tablet
- Take one tablet by mouth as soon as possible and no later than 5 days (120 hours) after unprotected sex or contraceptive failure. Take the tablet without delay.
- You can take the tablet at any time in your cycle.
- You can take the tablet at any time of the day either before, during or after a meal.
- If you are using one of the medicines that may prevent Ulipristal Acetate Rowex from working properly (see section 2 “What you need to know before you take Ulipristal Acetate Rowex”) or if you have used one of these medicines in the past 4 weeks, Ulipristal Acetate Rowex may work less effectively for you. Speak to your doctor or pharmacist before using Ulipristal Acetate Rowex. Your doctor may prescribe another type of (non-hormonal) emergency contraceptive, i.e. a Cu-IUD.

If you vomit after taking Ulipristal Acetate Rowex
If you vomit (be sick, throw up) within 3 hours of taking the tablet, take another tablet as soon as possible.

If you have sex again after taking Ulipristal Acetate Rowex
If you have unprotected sex after taking the tablet, it will not stop you from becoming pregnant. After you take the tablet and until your next period comes, you should use condoms every time you have sex.

If your next period is late after taking Ulipristal Acetate Rowex
After taking the tablet, it is normal for your next period to be a few days late.
However, if your period is more than 7 days late; if it is unusually light or unusually heavy; or if you experience symptoms such as abdominal (stomach) pain, breast tenderness, vomiting or nausea, you may be pregnant. You should do a pregnancy test right away. If you are pregnant, it is important that you see your doctor. (See section "Pregnancy, breast-feeding and fertility").

If you take more Ulipristal Acetate Rowex than you should
There have been no reports of harmful effects from taking a higher dose than recommended of this medicine. However do ask your pharmacist, doctor or other healthcare professional for advice.
If you have any further questions on the use of this medicine, ask your pharmacist, doctor or other healthcare professional.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Some symptoms such as breast tenderness and abdominal (stomach) pain, throwing up (vomiting), feeling sick (nausea) are also possible signs of pregnancy. If you miss your period and experience such symptoms after taking Ulipristal Acetate Rowex, you should do a pregnancy test (see section 2 "Pregnancy, breast-feeding and fertility").

Common side effects (may affect up to 1 in 10 people)
- nausea, abdominal (stomach) pain or discomfort, vomiting
- painful periods, pelvic pain, breast tenderness
- headache, dizziness, mood swings
- muscle pain, back pain, tiredness.

Uncommon side effects (may affect up to 1 in 100 people)
- diarrhoea, heartburn, wind, dry mouth
- unusual or irregular vaginal bleeding, heavy/prolonged periods premenstrual syndrome, vaginal irritation or discharge, lesser or greater sex drive
- hot flushes
- appetite changes, emotional disorders, anxiety, agitation, trouble sleeping, sleepiness, migraine, visual disturbances
- influenza
- acne, skin lesions, itching
- fever, chills, malaise.

Rare side effects (may affect up to 1 in 1,000 people)
- genital pain or itching, pain during sex, rupture of an ovarian cyst, unusually light period
- loss of concentration, vertigo, shaking, disorientation, fainting

- unusual sensation in eye, red eye, sensitivity to light
- dry throat, disturbance in taste
- feeling thirsty
- allergic reactions such as rash, hives or swelling of the face.

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 national reporting system: 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 Ulipristal Acetate Rowex

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 and on the blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.
Keep the blister in the outer carton in order to protect from light.

Do not throw away any medicines via wastewater or household waste. 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 Ulipristal Acetate Rowex contains
- The active substance is ulipristal acetate. Each film-coated tablet contains 30 mg ulipristal acetate.
- The other ingredients are
  Tablet core: lactose monohydrate, pregelatinised starch (maize), sodium starch glycolate (Type A), magnesium stearate (E470b).
  Tablet coating: hypromellose (E464), hydroxypropylcellulose (E463), stearic acid (E570), talc (E553b), titanium dioxide (E171).

What Ulipristal Acetate Rowex looks like and contents of the pack
Round, white, biconvex, film-coated tablet, embossed with "U30" on one side, with a diameter of approximately 9 mm and thickness of 4.5 mm.

The tablets are packed in PVC/PVDC/Aluminium blister of 1 film-coated tablet and inserted in a carton.

Marketing Authorisation Holder and Manufacturers
Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers
Salutas Pharma GmbH., Otto-von-Guericke-Allee 1, Barleben, Sachsen-Anhalt 39179, Germany.

Haupt Pharma Münster GmbH., Schleebrüggenkamp 15, Münster 48159, Germany.
Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

This medicinal product is authorised in the Member States of the European Economic Area under the following names:

Austria	Ulipristal acetate Hexal 30 mg – Filmtabletten
Belgium	Ulipristalacetaat Sandoz 30 mg filmomhulde tabletten
Estonia	Ulipristal acetate Sandoz
Ireland	Ulipristal Acetate Rowex 30 mg film-coated tablets
Latvia	Ulipristal acetate Sandoz 30 mg apvalkotās tabletes
Lithuania	Ulipristal acetate Sandoz 30 mg plėvele dengta tabletė
The Netherlands	Ulipristalacetaat Sandoz 30 mg, filmomhulde tablet

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USEFUL INFORMATION ABOUT CONTRACEPTION

MORE ABOUT EMERGENCY CONTRACEPTION

The sooner you take emergency contraception, the better the chance of avoiding pregnancy.
Emergency contraception will not affect your fertility.

Emergency contraception can delay ovulation within a given menstrual cycle, but it will not stop you from becoming pregnant if you have unprotected sex again. After you take emergency contraception and until your next period comes, you should use a condom every time you have sex.

MORE ABOUT REGULAR CONTRACEPTION

If you have taken emergency contraception and you do not use a regular contraceptive method (or do not have a contraceptive method that suits you), talk to your doctor or family planning clinic for advice. There are many different types of contraception available, and you should be able to find the right method for you.
Examples of regular contraception methods:

Daily methods	
Contraceptive pill	
Weekly or monthly methods	
Contraceptive patch	Vaginal Ring
Long lasting methods	
Contraceptive implant	IUD (intrauterine device)