

Ella[®] 30mg Tablet

Ulipristal acetate 30mg

Consumer Medication Information Leaflet (RiMUP)

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1. What Ella is used for

Ella is an emergency contraceptive intended to prevent pregnancy after unprotected sex or if your contraceptive method has failed. For example:

- if you 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.

This medicine is suitable for any woman of childbearing age, including adolescents. You can take the tablet at any time in the menstrual cycle.

2. How Ella works

Ella 30mg tablet 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.

Ella 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.

Ella is not used for regular contraception.

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 doctor for advice if you are worried about this.

3. Before you take Ella

When you must not use it

- If you are allergic to *ulipristal acetate* or any of the other ingredients of this medicine (see section "Product Description")

Before you start to use it

Talk to your pharmacist, doctor or other healthcare professional

- if your period is late or you have symptoms of pregnancy (heavy breasts, morning sickness), as you may already be pregnant
- if you suffer from severe asthma
- if you suffer from severe liver disease
- if you have been told by your doctor or other healthcare

professional that you have an intolerance to some sugars (i.e. *lactose*)

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, Ella is still recommended for all women regardless of their weight or BMI.

If you are taking other medicines

Contraceptives:

Ella 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.

Tell your pharmacist, doctor or other healthcare professional if you are taking or have recently taken any other medicines, including medicines obtained without a prescription or herbal medicines.

Some medicines may prevent Ella from working effectively. If you have used any of the medicines listed below during the last FOUR (4) weeks, Ella 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*,

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phenobarbital, phenytoin,
fosphenytoine, 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*).

4. How to take Ella

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 much to use and when to use it

- Take one tablet by mouth as soon as possible and no later than 5 days (120 hours) after unprotected sex or contraceptive failure.
- 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 Ella from working properly (see section "Taking other Medicines"). Speak to your doctor or pharmacist before using Ella. Your doctor may prescribe another type of (non-hormonal) emergency contraceptive, i.e. a Cu-IUD.

If you take more Ella than you should (overdose)

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 health professional for advice. If you have any further questions on the use of this medicine,

ask your pharmacist, doctor or other health professional.

5. While You are Using It

Things you must do

- If you vomit (be sick, throw up) within 3 hours of taking Ella, take another tablet as soon as possible.
- 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.
- It is normal for your next period to be a few days late after taking Ella. 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.

Things you must not do

- Do not breast-feed for one week after taking Ella. (see section "Things to be careful")

Things to be careful of

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.

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.

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.

This medicine will not affect your future fertility. If you have unprotected sex after taking the tablet, 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.

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

6. 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 Ella, you should do a pregnancy test (see section "Things to be

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careful”).

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
- allergic reactions such as rash, hives or swelling of the face
- feeling thirsty

Reporting of side effects

If you get any side effects, talk to your pharmacist, doctor or other healthcare professional. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can provide more information on the

safety of this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers' Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI).

7. Storage and disposal of Ella

Keep this medicine out of the sight and reach of children.

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

Store at or below 30°C. Store in the original package in order to protect from moisture. Keep the blister in the outer carton in order to protect from light.

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

8. Other information

Product description

Ella 30mg tablet is a white to marble creamy, round curved tablet engraved with “ella” on both sides.

Ella is available in a carton containing one blister of 1 tablet.

Ingredients

- The active substance is *ulipristal acetate*. Each tablet contains 30 milligrams of *ulipristal acetate*.
- The other ingredients are *lactose monohydrate*, *povidone K30*, *croscarmellose sodium*, *magnesium stearate*.

MAL number

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