PATIENT INFORMATION LEAFLET FOR ELLA

SCHEDULING STATUS: S2

Ella 30 mg tablet (uncoated)

Ulipristal acetate

Contains sugar (lactose monohydrate 237 mg/tablet).

Read all of this leaflet carefully because it contains important information for you

ELLA is available without a doctor's prescription, for you to use in situations as described under section 1. "What ELLA is and what it is used for". Nevertheless, you still need to use ELLA carefully to get the best results from it. Keep this leaflet. You may need to read it again.

- Do not share ELLA with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

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

1. What ELLA is and what it is used for

ELLA is an emergency contraceptive

ELLA 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 you should.

You should take the tablet as soon as possible after sex, and within a maximum of 5 days (120 hours).

This is because it is more effective if you take it as soon as possible after unprotected sex.

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

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

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 provider 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 to be used for regular contraception

If you do not have a regular method of contraception, talk to your doctor or healthcare provider to choose one that is suitable for you.

How ELLA works

ELLA 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 provider for advice if you are worried about this.

2. What you need to know before you take ELLA

Do not take ELLA

If you are hypersensitive (allergic) to ulipristal acetate or any of the other ingredients of ELLA (listed in section 6).
If you suspect that you are pregnant.

Warnings and precautions

Talk to your pharmacist, doctor or other healthcare provider 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, breastfeeding 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, ELLA is still recommended for all women regardless of their weight or BMI.
You are advised to speak to a healthcare provider if you are concerned about any problems related to taking emergency contraception.
If you become pregnant despite taking the tablet, it is important that you see your doctor. See section “Pregnancy, breastfeeding and fertility” for more information.

Other medicines and ELLA

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)
Some medicines may prevent ELLA from working effectively. If you have used any of the medicines listed below during the last 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, 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 ELLA when you use (or have recently used) any of the medicines stated above.

Other contraceptives and ELLA

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.

Pregnancy, breastfeeding 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 healthcare provider for advice before taking this medicine.

Pregnancy

Before taking this medicine, if your period is late, tell your pharmacist, doctor or other healthcare provider, 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 ELLA, you or your healthcare provider are encouraged to report it.
You can report a pregnancy to Cipla Medpro (Pty) Ltd at drugsafetysa@cipla.com or telephone 080 222 6662 (toll free).
You can also report a pregnancy to SAHPRA via the “Med Safety APP” (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Breastfeeding

If you take this medicine while you are breastfeeding a baby, do not breastfeed for one week after taking this medicine. During this time, you should use a breast pump in order to maintain milk production but throw away your breast milk. The effect of breastfeeding 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 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.

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.

ELLA contains lactose

If you have been told that you have an intolerance to some sugars, tell your doctor, pharmacist or other healthcare provider before taking this medicine.

ELLA contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'

3. How to take ELLA

Do not share medicines prescribed for you with any other person.

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

How to take the ELLA tablet

Take one (1) 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 ELLA from working properly (see section 2 "What you need to know before you take ELLA") or if you have used one of these medicines in the past 4 weeks, ELLA may work less effectively for you. 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 vomit after taking ELLA

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 ELLA

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 ELLA

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, breastfeeding and fertility”)

If you take more ELLA 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 provider for advice.
If you have any further questions on the use of this medicine, ask your pharmacist, doctor or other healthcare provider.
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

4. Possible side effects

ELLA can have side effects.

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 2 “Pregnancy, breastfeeding and fertility”).
Not all side effects reported for ELLA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ELLA, please consult your healthcare provider for advice.

Frequent 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

Less frequent 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

Other 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

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

Reporting of side effects

If you experience side effects, talk to your doctor or pharmacist.

You can report side effects to Cipla Medpro (Pty) Ltd at drugsafetysa@cipla.com or telephone 080 222 6662 (toll free).

You can also report side effects to SAHPRA via the “Med Safety APP” (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of ELLA.

5. How to store ELLA

Store all medicines out of reach of children.

Store at or below 25 °C. Store in the original packaging to protect from moisture. Keep the blister in the outer carton to protect from light.

Do not use after the expiry date stated on the blister and carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ELLA contains

The active substance is ulipristal acetate. Each tablet contains 30 mg of ulipristal acetate.

The other ingredients are lactose monohydrate, povidone, croscarmellose sodium, magnesium stearate.

What ELLA looks like and contents of the pack

ELLA 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.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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