

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr**ella**®

ulipristal acetate tablet

Read this carefully before you start taking **ella** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ella**.

What is ella used for?

You must use **ella** within 5 days (120 hours) to prevent pregnancy after:

- you had unprotected sex
- your method of birth control has failed. For example:
 - you or your partner's condom tore, slipped or came off
 - you did not take your birth control pill the right way

You should not use **ella** in place of a regular birth control method.

How does ella work?

Ulipristal acetate (the active ingredient in **ella**) is in a class of medications called progestins. It works by modifying the activity of the natural hormone progesterone. Progesterone is necessary for the release of an egg during the monthly cycle (ovulation). As a result, this medicine works by preventing or delaying ovulation.

ella is an emergency contraceptive. It is a way to prevent pregnancy if you had sex without using birth control or your birth control method failed.

ella is not effective in every case. Of 100 women who take this medicine approximately 2 will become pregnant.

ella prevents pregnancy from starting. It does not end a pregnancy that has already started (this means that **ella** will not work if you are already pregnant).

What are the ingredients in ella?

Medicinal ingredient: Ulipristal acetate

Non-medicinal ingredients: Croscarmellose sodium, lactose monohydrate, magnesium stearate, and povidone K30.

ella comes in the following dosage forms:

Tablet, 30 mg

Do not use ella if:

- you are allergic to:
 - ulipristal acetate
 - any of the other ingredients of this medicine, or the component of the container

See “What are the ingredients in **ella**?”

- you are pregnant or suspect a pregnancy

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ella. Talk about any health conditions or problems you may have, including if :

- your period is late or you have symptoms of pregnancy (heavy breasts, morning sickness), as you may already be pregnant
- you have severe liver disease
- you are lactose intolerant. **ella** contains lactose.
- you are breast feeding. Do not breastfeed your baby for one week after taking **ella**. During this time, pump and discard your breast milk in order to stimulate and maintain milk supply.

Other warnings you should know about:

- The sooner you take **ella**, the better it works, so take it **as soon as** possible after unprotected sex, and within a maximum of 5 days (120 hours).
- It is very important that you have a reliable form of birth control that is right for you. If you do not have a regular birth control method, talk to your healthcare professional to choose one that is suitable for you.
- **ella** does not prevent pregnancy in every case. If you become pregnant despite taking the tablet, it is important that you see your healthcare professional
- **ella** is only effective for one episode of unprotected sex. Right after using **ella**, you are again able to get pregnant. To prevent pregnancy after taking **ella**, you should use a reliable barrier birth control method (such as condoms) every time you have sex for the rest of your menstrual cycle (e.g. time between taking **ella** and your next period).
- after taking **ella**, you may wish to **resume** the **hormonal** birth control (such as birth control pill, patch, ring) that you usually take or **start a new hormonal** birth control. In any case, be sure to:
 - **wait 5 days** before doing so
 - and
 - use condoms every time you have sex until your next period
- If you used **ella** because you had a problem with your hormonal birth control (e.g. birth control failure), follow the instructions provided in the patient medication information leaflet for that specific hormonal birth control product or contact your healthcare professional for further information. Be sure to use condoms each time you have sex until your next menstrual period.
- Do not use **ella** twice in the same menstrual cycle.
- **ella** is not for frequent or regular use to prevent pregnancy. If you need to use emergency birth control often, talk with your healthcare professional.
- **ella** does not end a pregnancy that has already started. Talk to your healthcare professional if you think you may already be pregnant.

- **ella** will not protect you against sexually transmitted diseases (STDs):
 - HIV infection (AIDS)
 - other sexually transmitted diseases (STDs) (e.g. chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B and syphilis).

Only condoms can protect you from sexually transmitted infections.

- Before you take **ella**, tell your doctor if your last period was not normal. You may already be pregnant.
- **Next period after use of ella:** After taking **ella**, it is normal for your next period to be a few days late. However, you may be pregnant if:
 - your period is more than 7 days late; if it is unusually light or unusually heavy;
 - you experience symptoms such as abdominal (stomach) pain, breast tenderness, vomiting or nausea.

You should do a pregnancy test right away in the case of either of the above scenarios. If you are pregnant, it is important that you see your healthcare professional.

- If you have unprotected sex after taking **ella**, it will not stop you from becoming pregnant. Unprotected sex at any time during your cycle can lead to pregnancy.
- **Driving and using machines:** After taking **ella**, you may have dizziness, drowsiness, blurred vision and/or loss of concentration. If you experience these symptoms, do not drive or use machines
- **ella** contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ella:

- medicines used to treat epilepsy (e.g., phenytoin, phenobarbital, carbamazepine, barbiturates, felbamate, oxcarbazepine, topiramate)
- rifampin, rifampicin (antibiotic used to treat tuberculosis)
- bosentan (used to treat a condition known as pulmonary hypertension)
- griseofulvin (an antibiotic used to treat certain skin infections)
- dabigatran etexilate (used to prevent blood clots)
- digoxin (used to treat various heart conditions)
- esomeprazole (used to treat gastric acidity (heartburn))
- St John's wort/*Hypericum perforatum*
- ritonavir (used to treat HIV)
- itraconazole, ketoconazole (used to treat mycosis (fungal infections))

- Other birth control methods. These include
 - hormonal birth controls like birth control pill, patch, or ring. **ella** may make your hormonal birth control less effective. Be sure to:
 - **wait 5 days** before **starting** a new birth hormonal control or **resuming** the hormonal birth control that you usually take
 - and
 - always use reliable barrier birth control method (such as condoms) every time you have sex from the time between taking ella and until your next period.
- emergency birth control pills that contain levonorgestrel. Do not take **ella** together with another birth control pill that contains levonorgestrel. By taking them both together, you might make **ella** less effective.

How to take ella:

- You should take ella as soon as possible and within a maximum of 5 days (120 hours)
- Follow your healthcare professional's instructions very carefully.
- you can take **ella** tablet
 - at any time during the menstrual cycle.
 - by mouth with or without food.
- If you vomit within 3 hours of taking **ella**, contact your healthcare professional immediately in order to take another tablet.

Usual dose:

Take one tablet by mouth **as soon as possible** within 5 days (120 hours) after unprotected sex or if you had a birth control failure.

Overdose:

If you have taken too much **ella**,

- you may have a shortened menstrual cycle (this mean you may have your period 2-3 days earlier than expected)
- your period may last longer than usual with spotting.

If you think you, or a person you are caring for, have taken too much **ella** contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using ella?

These are not all the possible side effects you may have when taking **ella**. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- acne
- back pain
- breast tenderness
- dizziness
- fatigue
- headache
- menstrual pain (dysmenorrhea)
- mood disorders
- muscle pain
- nausea
- pelvic pain
- stomach (abdominal) pain
- stomach (abdominal) discomfort
- vomiting

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE			
Hypersensitivity reactions: difficulty swallowing or breathing, wheezing, drop in blood pressure, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue or throat			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

This package is sealed for your protection. Do not use if torn or broken.

Store at 15-25°C. Store in the original packaging to protect from moisture.

Keep the blister in the outer carton in order to protect from light.

Keep out of reach and sight of children.

If you want more information about ella:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website www.abbvie.ca, or by calling 1-888-704-8271.

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