

# **PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

This medicine is dispensed without a doctor's prescription

## **Ella**

### **Tablet**

Each tablet contains: Ulipristal Acetate 30 mg

Inactive ingredients – see section 6.

Patient safety information card:

In addition to the leaflet, there is a patient safety information card for Ella. This card contains important safety information you should know before and after taking Ella, as well as act according to it. Please review the patient safety information card and the patient leaflet before taking the medicine. You should keep the leaflet and the card for further review, if necessary.

**Read the entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or the pharmacist.

**The medicine is dispensed without a doctor's prescription for women and girls above the age of 14. For girls under the age of 14, the medicine is dispensed with a doctor's prescription only.**

Take the product according to the instructions in the dosage section of this leaflet. Consult the pharmacist if you need further information.

The medicine should be taken immediately after sexual intercourse but no later than 120 hours (5 days), since the efficacy of the medicine is higher the closer it is taken to the time of unprotected sexual intercourse. Ella is not effective in every case: out of 100 women who take this medicine, approximately 2 may become pregnant.

Ella may be taken in any stage of the menstrual cycle (every day of the month).

**Ella is not intended to be a contraceptive for routine use.** Consult a doctor in order to determine a regular method for preventing pregnancy.

Ella does not work if you are already pregnant.

Ella is ineffective in cases of unprotected intercourse after it has been taken.

### **1. What is Ella intended for?**

Ella is an emergency contraceptive for up to 120 hours (5 days) after unprotected intercourse or failure of the contraceptive that was used (e.g. if the condom slipped off, tore or if you forgot to use one, or if you forgot to take pills on time, see the patient's leaflet of the contraceptive pills).

**Therapeutic class:** a selective modulator of the progesterone receptor.

Ella contains the active ingredient Ulipristal acetate, which acts by altering the natural activity of progesterone, which is necessary for the ovulation process. Consequently, Ella postpones the ovulation.

### **2. Before using Ella:**

#### **X Do not use Ella if:**

- You are sensitive (allergic) to Ulipristal acetate (the active ingredient) or any of the additional components, which the medicine contains (see section 6).

#### **! Special warnings regarding the use of the medicine:**

**Before using Ella, tell the doctor if:**

- The menstrual cycle is late or if you are feeling signs of pregnancy (morning sickness, breasts sensitivity), since you might be pregnant. **The medicine does not prevent an existing pregnancy.**
- You are suffering from severe asthma.
- You are suffering from a severe liver disease.

You should take Ella as soon as possible after unprotected intercourse. There is evidence that Ella may be less effective as the woman's weight or Body Mass Index (BMI) increases, but this evidence is inconclusive. Therefore, Ella is recommended to all women, regardless of weight or BMI.

- **The medicine should only be used as an emergency contraceptive** (as backup), and does not replace under any circumstances the regular use of contraceptives. It is recommended to consult a doctor about contraceptives for routine use that will be suitable for you.
- Taking Ella may temporarily reduce the efficacy of hormonal contraceptives, such as contraceptive pills or patches. After taking the medicine, it is recommended to use a mechanical contraceptive (e.g. condom) in any sexual intercourse until the occurrence of the next menstrual cycle, even if you are also using the hormonal contraceptives.
- Ella should not be used alongside other emergency contraceptives (which contain an ingredient called Levonorgestrel). Taking another emergency contraceptive may reduce the efficacy of Ella.

Ella is ineffective in cases of unprotected intercourse after it has been taken.

Unprotected intercourse at any time during that month may lead to pregnancy.

- In case you become pregnant after using the medicine, as with any pregnancy, you should see a doctor (see the "pregnancy, breastfeeding and fertility" section).
- **The medicine does not provide any protection against contracting HIV or any other sexually-transmitted infections.** Only use of a condom may protect you from these diseases. If you are worried that you have been infected with this kind of disease – contact the doctor.

### **! Drug interactions:**

**If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, tell the doctor or the pharmacist.**

Some medicines may decrease the efficacy of Ella. In these cases, the doctor may decide to prescribe you with another type of non-hormonal emergency contraceptive (such as an intrauterine device containing copper).

Especially inform the doctor or the pharmacist if you are taking or have taken the following medicines during the last 4 weeks:

- Certain medicines for treatment of epilepsy (such as phenytoin, fosphenytoin, primidone, oxcarbazepine, carbamazepine, phenobarbital and barbiturates).
- Certain medicines for treatment of AIDS (such as Ritonavir, Efavirenz, Nevirapine).
- Certain medicines for treatment of tuberculosis (for example: Rifampicin, Rifabutin).
- A medicine for treatment of fungal infections (griseofulvin).
- Herbal medicines containing Hypericum (St. John's Wort) for treatment of depression and anxiety.
- Do not use the medicine concomitantly with an emergency contraceptive that contains the hormone Levonorgestrel. Taking these two medicines together may reduce the efficacy of Ella.

- Ella may reduce the efficacy of hormonal contraceptives (such as birth control pills and patches). Therefore you should use mechanical contraceptives (such as condoms) in addition until the next menstrual cycle occurs.

**! Using the medicine Ella and food**

Ella may be taken before, with or after a meal.

**! Pregnancy, breastfeeding and fertility**

Pregnancy

Before taking Ella, if your period is late, you should inform the doctor or pharmacist, or perform a pregnancy test in order to rule out an existing pregnancy (see the “special warnings regarding the use of the medicine” section).

Ella is a contraceptive used to prevent pregnancy from starting. If you are already pregnant, Ella **does not** terminate an existing pregnancy.

If you become pregnant despite taking Ella, there is no evidence that Ella might affect your pregnancy.

If you become pregnant despite using the medicine, as in any pregnancy, you should see the doctor in order to make sure the pregnancy is not outside the womb. This is particularly important if you are developing severe abdominal pain or bleeding, or if you had a pregnancy outside the womb, tubal surgery or chronic genital infection.

Breastfeeding

You should not breastfeed for a week after taking the medicine. During that time it is recommended to pump and discard the milk in order to stimulate and retain the ability to breastfeed. After taking the medicine the effect of breastfeeding on the baby is unknown for a week.

Fertility

Ella will not affect your future fertility. Ella is ineffective in cases of unprotected intercourse after it has been taken. Therefore, it is very important to use a barrier contraceptive such as condoms (see “special warnings regarding use of the medicine”) until the occurrence of the next menstrual cycle.

After using the medicine, if you wish to start or continue taking hormonal contraceptives such as contraceptive pills, you may do it, but you will have to use a barrier contraceptive such as a condom or diaphragm until your next period occurs.

**! Driving and operating machinery**

Using this medicine may cause dizziness, blurry vision, drowsiness and/or impaired concentration (see “side effects” section). If you feel these effects, you should not drive a vehicle, operate dangerous machinery and perform any activity that requires alertness.

**! Important information about some of the ingredients of the medicine**

The medicine Ella contains lactose monohydrate.

If you were told by the doctor that you are suffering from intolerance to certain sugars, you should consult a doctor before taking the medicine.

This medicine contains less than 23 mg of sodium per tablet, and is therefore considered sodium-free.

**3. How should you use Ella?**

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The commonly accepted dose is one tablet, as soon as possible, but no later than 120 hours (5 days) after unprotected sexual intercourse or a failure of contraceptive that was being used.

If you are using hormonal contraceptives, keep taking them as usual (regardless of taking the medicine).

**Do not exceed the recommended dose.**

- The medicine should be taken with water. No information is available regarding crushing/halving/chewing the tablet.
- The medicine may be taken in any stage of the period (every day of the month).
- If you are taking any of the medicines listed in section 2 (“Before using Ella”), or if you have used any of these medicines during the past 4 weeks, Ella may be less effective for you.

The doctor may decide to prescribe you with another type of non-hormonal emergency contraceptive (such as an intrauterine device containing copper). Consult with the doctor or the pharmacist before taking the medicine.

- In case of vomiting within 3 hours of taking the medicine, a second tablet should be taken as soon as possible.
- Ella is ineffective in cases of unprotected intercourse after it has been taken. After taking the medicine, a barrier contraceptive such as a condom should be used every time you have unprotected sexual intercourse.
- After taking this medicine, the next period may be several days late.
- If the period is more than 7 days late, or if there is an abnormal bleeding (very light or very massive) during the next cycle, or if abdominal pain, vomiting, nausea, breasts tenderness occur, you may be pregnant. A pregnancy test should be performed immediately. If you are pregnant, contact the doctor.

#### **If you take a higher dosage**

No harmful effects of taking a higher dose than the recommended dose for Ella have been reported, but if you took an overdose or by mistake a child swallowed this medicine, go immediately to the doctor or the emergency room of a hospital and take the package of the medicine with you.

**Do not take medicines in the dark! Check the label and the dosage every time you take the medicine. Wear glasses if you need them.**

**If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.**

#### **4. Side effects:**

As with any medicine, using Ella may cause side effects in some users. Do not be alarmed when reading the list of side effects, you may not experience any of them.

Some of the side effects, such as breasts tenderness, abdominal pain, vomiting and nausea, may also be signs of pregnancy. If your monthly cycle is late and you experience these symptoms after taking the medicine, you should perform a pregnancy test.

Common side effects - side effects that occur in 1-10 out of 100 users:

- Nausea, vomiting, abdominal pain or abdominal discomfort.
- Menstrual cramps, pelvic pain, breasts tenderness.
- Headache, lightheadedness, mood swings.
- Myalgia (muscle pain), back pain, tiredness.

Uncommon side effects - side effects that occur in 1-10 out of 1,000 users:

- diarrhea, heartburn, dry mouth, bloating in the digestive system (flatulence).
- Abnormal or irregular vaginal bleeding, prolonged or more massive than usual menstrual bleeding, premenstrual syndrome, vaginal discharge, vaginal irritation, changes in libido.
- Hot flashes.
- Changes in appetite, emotional disorders, anxiety, agitation, trouble sleeping, sleepiness, migraine, visual disturbances.
- Influenza.
- Acne, skin sores, itch.

- Fever, chills, feeling sick.

Rare side effects - side effects that occur in 1-10 out of 10,000 users:

- Pain or itching in the genitals, pain during intercourse, rupture of an existing ovarian cyst, unusually light periods.
- Concentration disturbances, vertigo, tremor, disorientation, fainting.
- Unusual sensation in the eye, red eye, sensitivity to light.
- Dry throat, change in the sense of taste.
- Allergic reactions such as rash, hives, or swelling in the face.
- Thirst.

**If a side effect occurs, or if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.**

Side effects may be reported to the Ministry of Health by clicking on the link “report side effects due to medicinal treatment” found on the Ministry of Health website homepage ([www.health.gov.il](http://www.health.gov.il)), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il/>

## **5. How to store the medicine?**

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (EXP) appearing on the package. The expiry date refers to the last day of that month.
- Store in a temperature below 25°C, in the original package, in order to protect from light and moisture.

## **6. Additional information:**

In addition to the active ingredient the medicine also contains:

Lactose Monohydrate, Povidone K30, Croscarmellose Sodium, Magnesium Stearate

- Each tablet contains 237 mg lactose monohydrate.

**What does the medicine look like and what are the contents of the package:**

Ella is a round, cream-white tablet on which “ella” is printed on both sides.

Each package contains one tablet.

**Marketing authorization holder and importer:** CTS Ltd., 4 Haharash St., Hod Hasharon.

**Manufacturer:** Laboratoire HRA Pharma, Chatillon, France.

This leaflet was revised in 03/2022 in accordance with the Ministry of Health guidelines.

**Registration number of the medicine in the National Drug Registry of the**

**Ministry of Health:** 146-39-33469