Package leaflet: Information for the user

Levonorgestrel Teva 1.5 mg Tablet

levonorgestrel

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:
1. What Levonorgestrel Teva is and what it is used for
2. What you need to know before you use Levonorgestrel Teva
3. How to use Levonorgestrel Teva
4. Possible side effects
5. How to store Levonorgestrel Teva
6. Contents of the pack and other information

1. What Levonorgestrel Teva is and what it is used for

Levonorgestrel Teva is an oral emergency contraceptive.

What is emergency contraception?

Emergency contraception is a rescue method intended to prevent pregnancy after unprotected intercourse or in case of failure of a contraceptive method.

When should emergency contraception be used?

This contraceptive method should be used as soon as possible, preferably within 12 hours and no later than 72 hours (3 days), after unprotected sexual intercourse or failure of a contraceptive method. It is more effective if you take it as soon as possible after unprotected sex. Levonorgestrel Teva can only prevent you becoming pregnant if you take it within 72 hours of unprotected sex. It does not work if you are already pregnant. If you have unprotected sex after taking Levonorgestrel Teva, it will not stop you from becoming pregnant.

Levonorgestrel Teva has been shown to prevent 52% to 85% of expected pregnancies.

Levonorgestrel Teva may be used in these cases:
- if you have had sexual intercourse without any contraception;
- if you have forgotten to take your regular contraceptive pill on time;
- if your partner's condom has broken, slipped or came off;
- if you fear that your intrauterine device has been expelled;
- if your vaginal diaphragm or your contraceptive cap has moved or if you have removed it early;
- if you are worried that the method of coitus interruptus or the rhythm method has failed;
- in the event of rape.

Levonorgestrel Teva works by stopping your ovaries from releasing an egg. It cannot stop a fertilized egg from attaching to the womb.

This tablet is **only for emergency contraception**, not for regular contraception as it is less effective than the regular contraceptive pill ("the pill").

Levonorgestrel TevaLevonorgestrel Teva is not indicated for use before the first menstrual bleeding (menarche).

2. What you need to know before you use Levonorgestrel Teva

Do not use Levonorgestrel Teva

- if you are allergic to levonorgestrel or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Levonorgestrel Teva.

The use of Levonorgestrel Teva is not recommended in the following cases:
- if you have had a tubal (ectopic) pregnancy,
- if you have had an infection in your fallopian tubes (salpingitis),
- if you have personal or family history of known risk factor for thrombosis (blood clotting).
- if you have a severe digestive disease which impairs absorption of food and medications,
- if you have severe liver problems or severe disease of the small bowel, such as Crohn's disease.-

A previous ectopic pregnancy and a previous infection of the fallopian tubes increase the risk of a new ectopic pregnancy. Therefore, if you have had an ectopic pregnancy or an infection of the fallopian tubes you should contact your doctor before taking Levonorgestrel Teva.

Emergency contraception must be used only occasionally and should not replace a regular contraceptive method because:
- it does not prevent pregnancy in every instance;
- there is a risk of hormonal overdose which may cause disturbance to your menstrual cycle with regular intake.

Emergency contraception cannot interrupt a pregnancy.

If you have had another act of unprotected intercourse more than 72 hours ago, you may already be pregnant. Treatment with Levonorgestrel Teva following the second act of intercourse may therefore be ineffective in preventing pregnancy.

Repeated administration of Levonorgestrel Teva within a menstrual cycle is not advisable because it may upset your cycle.

Levonorgestrel Teva does not work as well as regular methods of contraception. Your doctor can tell you about long-term methods of contraception which are more effective in preventing from getting pregnant.

In all women, emergency contraception should be taken as soon as possible after unprotected intercourse. There is some evidence that <invented name> may be less effective with increasing body weight or body mass index (BMI), but these data were limited and inconclusive. Therefore, <invented name> 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.

After taking this medicine:
It is mandatory to exclude pregnancy by performing a pregnancy test:
- if your next menstrual period is delayed more than five days,
- in case of abnormal bleeding even at the date of expected menstrual period.

If you did not use a condom (or if it split or slipped off) during intercourse, it might be possible that you have contracted a sexually transmitted disease or the HIV virus. **The use of emergency contraception does not protect against sexually transmitted diseases** and cannot replace the necessary precautions and measures to be taken in case of risk of transmission (see National Information)

Children and adolescents

Children
Levonorgestrel Teva is not indicated for use before the first menstrual bleeding (menarche).

Other medicines and Levonorgestrel Teva

The medicines listed below, including medicines obtained without prescription, can reduce or suppress the effectiveness of Levonorgestrel Teva:
- Certain medicines used to treat epilepsy (phenobarbital, phenytoin, primidone, carbamazepin),
- Certain medicines used to treat HIV infection (ritonavir),
- Certain medicines to treat certain infections (rifabutin, rifampicin, griseofulvin),
- Herbal medicines containing St. John's Wort (*Hypericum perforatum)*
- A medicine called cyclosporin (suppresses the immune system)

Levonorgestrel Teva should not be used together with drugs containing ulipristal acetate.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, or think you may be pregnant, ask your doctor or pharmacist for advice before taking this medicine

If you are pregnant:

This medication does not end an ongoing pregnancy.
If you take this medication and you still become pregnant, studies to date have not shown any risk of malformation for the developing foetus. However **this medication should not be taken if you are pregnant**.

If you do become pregnant after taking Levonorgestrel Teva, you should contact your doctor. Your doctor might want to check that the pregnancy is not ectopic (the baby develops somewhere outside your womb). This is especially important if you develop severe pain in your abdomen after taking Levonorgestrel Teva or if you ever had an ectopic pregnancy, surgery to your fallopian tubes or pelvic inflammation disease.

If you are breast-feeding:

Breast-feeding is possible. However, since levonorgestrel passes into breast milk, it is suggested that you breastfeed immediately before taking the Levonorgestrel Teva tablet and refrain from nursing for **at least 8 hours** following Levonorgestrel Teva administration.

Driving and using machines

After Levonorgestrel Teva intake, some women experienced fatigue and dizziness (see section 4 “Possible side effects”): do not drive or use machines if you experience these symptoms.

No studies on the effect on the ability to drive and use machines have been reported.

Levonorgestrel Teva contains lactose

Levonorgestrel Teva contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to use Levonorgestrel Teva

[For medicines available without a prescription:]

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

[For medicines available on prescription only:]

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

<[To be completed nationally]>

Levonorgestrel Teva is for oral use. The tablet should be taken with a glass of water and should not be chewed.

The tablet should be taken **as soon as possible, preferably within 12 hours, after unprotected intercourse** and no longer than 72 hours (3 days) after intercourse.

Levonorgestrel Teva can be taken at any time during the menstrual cycle assuming you are not already pregnant or think you may be pregnant.

If you vomit within three hours of taking the tablet, you should take another tablet immediately. Contact your pharmacist or doctor to obtain another tablet.

After using emergency contraception, you should use a local contraceptive method (condom, spermicide, cervical cap) until your next menstrual period. If another unprotected intercourse takes place after the use of Levonorgestrel Teva (also if this is during the same menstrual cycle), the tablet will not exert its contraceptive effect and there is again the risk of pregnancy.

If you take oral contraception (birth control pills), you should carry on taking your birth control pills as usual after using Levonorgestrel Teva. In case you do not have menstrual bleeding in the next pill-free period, perform a pregnancy test to exclude pregnancy, and see your doctor.

Your doctor can also tell you about longer-term methods of contraception which are more effective in preventing you from getting pregnant.

Use in children
Levonorgestrel Teva is not indicated for use before the first menstrual bleeding (menarche).

Your next period after you have taken Levonorgestrel Teva

After the use of Levonorgestrel Teva, your period is usually normal and will start on the expected day; however sometimes, this will be a few days later or earlier.

If your period is more than 5 days late or is unusually light or unusually heavy, or if you think that you might be pregnant for any other reason, you should check whether you are pregnant by performing a pregnancy test. If you do become pregnant even after taking this medicine, it is important that you see your doctor.

If you use more Levonorgestrel Teva than you should

No acute toxicity or serious harmful effects has been demonstrated with this medicine in case of intake of several doses. However, you may feel sick, actually be sick (vomit) or have vaginal bleeding. You should contact your doctor or pharmacist for advice.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, Levonorgestrel Teva can cause side effects, although not everybody gets them.

The following side effects have been observed:

Very common: may affect more than 1 in 10 people
- dizziness, headache
- nausea, abdominal pain
- breast tenderness, delay of period, heavy period, bleeding, uterine pain
- fatigue

Common: may affect up to 1 in 10 people
- diarrhoea, vomiting
- painful periods

Not known: frequency cannot be estimated from the available data
- cases of thromboembolic events (blood clotting) have been reported during the postmarketing period
- allergic reactions such as swelling of throat and face and skin rash can occur after taking this medicine

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Levonorgestrel Teva

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

This medicine does not require any special storage conditions.

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

Do not use Levonorgestrel Teva if you notice visible signs of deterioration; it should then be returned to your pharmacist.

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 to protect the environment.

6. Contents of the pack and other information

What Levonorgestrel Teva contains

The active substance is levonorgestrel. Each tablet contains 1.5 mg of levonorgestrel.

The other ingredients are lactose monohydrate (see section 2 "Levonorgestrel Teva contains lactose"), povidone, maize starch, silica colloidal anhydrous and magnesium stearate.

Levonorgestrel belongs to a group of medicines called emergency contraceptives.

What Levonorgestrel Teva looks like and contents of the pack

Levonorgestrel Teva is a round, white to off-white, uncoated flat tablet of 8 mm debossed with '145' on one side and the other side plain.

Each pack of Levonorgestrel Teva contains one tablet of 1.5 mg of levonorgestrel.

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This medicinal product is authorised in the Member States of the EEA under the following names:

Bulgaria	CHRONO 72 1,5 mg tablets
Czech Republic	SCHERZA 1,5 mg
Denmark	Levonorgestrel Teva
France	LEVONORGESTREL TEVA 1,5 mg, comprimé
Germany	LaPia
Ireland	Levonorgestrel Teva 1.5 mg Tablet
Italy	STEPIN
The Netherlands	Levonorgestrel Teva 1,5 mg, tabletten
Portugal	Levonorgestrel Teva
Spain	Levonorgestrel Teva 1,5 mg comprimido EFG
United Kingdom	Toomee 1.5 mg Tablets

This leaflet was last revised in October 2016.

<[Optional Additional National Information]>

NATIONAL INFORMATION

a) Some information about the menstrual cycle and contraception

- The menstrual cycle
The menstrual cycle is the time elapsed between two menstrual periods. Normally, the cycle lasts for 28 days although its length can vary noticeably from one woman to another. Menstrual periods occur when a woman is not pregnant.

- Fertilisation
At the middle of the cycle, an egg (ovum) is expelled by one of the 2 ovaries (this moment is called "ovulation").Usually ovulation takes place at the middle of the cycle, but it can occur at any moment during the cycle.
If sperm cells are near the ovum when it is released, fertilisation (i.e. fusion of a sperm cell with the ovum to form an embryo) can take place.
After a few days, the fertilised ovum implants in the womb and the pregnancy starts.

- Contraception
Contraceptive methods are aimed to prevent:
- ovulation : this is the case for the contraceptive pill,
- fertilisation (fusion of a sperm cell with the ovum): this is the case for condoms, or
- implantation of a fertilised ovum: this is the case for intrauterine devices.

- Emergency contraception pills
Emergency contraception pills act by blocking or delaying ovulation following sexual intercourse. They are not effective if ovulation has already occurred.

Whenever a woman has sexual intercourse without use of a contraceptive method, the possibility of a pregnancy cannot be excluded.

If you have taken this medicine but you do not use a regular contraceptive method, it is strongly recommended you visit your doctor or family planning clinic to obtain advice on a contraceptive method suitable for you.

b) Advice in case of risk of transmission of sexually transmitted disease

If you have unprotected sexual intercourse you may be at risk of contracting a sexually transmitted disease, particularly if you are unaware of your partner's sexual history or have multiple partners. If you have any questions, please ask your pharmacist, doctor or family planning clinic.

GLOSSARY

- Ectopic pregnancy: a pregnancy that develops outside of the uterus, usually in one of the fallopian tubes. Warning signs include persistent abdominal pain, missed menstrual periods, vaginal bleeding, signs of pregnancy (nausea, breast tenderness). If you experience such symptoms, consult your doctor immediately.

- Salpingitis: infection of the fallopian tubes. Symptoms include abdominal pain, fever and heavy vaginal discharge.