

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

Lornestin 1,50 mg tablet

Levonorgestrel

Contains sugar: Lactose monohydrate 120,0 mg

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

Lornestin is available without a doctor's prescription. Nevertheless, you still need to use Lornestin carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Lornestin 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 Lornestin is and what it is used for
2. What you need to know before you take Lornestin
3. How to take Lornestin
4. Possible side effects
5. How to store Lornestin
6. Contents of the pack and other information

1. What Lornestin is and what it is used for

Lornestin is an emergency contraceptive that can be used within 72 hours (3 days) of unprotected sex or if your usual contraceptive method has failed.

Lornestin tablet contains a synthetic hormone-like active ingredient called levonorgestrel. It works mainly by preventing fertilisation by changing the way sperm and/or the egg cell is transported. It may also cause changes in the womb to discourage implantation.

It has been estimated that Lornestin prevents 84 % of expected pregnancies when taken within 72 hours after having unprotected sex. If you are uncertain about the timing of unprotected sex or if you have had unprotected sex more than 72 hours earlier in the same menstrual cycle, conception may have occurred. Treatment with Lornestin following the second act of unprotected sex may therefore be ineffective in preventing pregnancy.

Lornestin is not as effective as a conventional regular method of contraception. If you think you need repeated courses of emergency contraception you should consider long-term methods of contraception.

2. What you need to know before you take Lornestin

Do not take Lornestin:

- If you are hypersensitive (allergic) to levonorgestrel or any of the other ingredients of this medicine (listed in section 6);
- If you have severe liver problems;
- If you are pregnant or suspect that you are pregnant;
- If you have depression, which is not well controlled with treatment;
- If you have had depression with previous use of hormonal contraceptives.

Warnings and precautions

Take special care with Lornestin if:

If you become pregnant even after taking this medicine, it is important to see your doctor. There is no evidence that Lornestin will harm a baby that develops in your womb, but your doctor may want to check that the pregnancy is not ectopic (where the baby develops somewhere outside the womb). This is especially important if you have severe abdominal

pain or if you have previously had an ectopic pregnancy, fallopian tube surgery or pelvic inflammatory disease.

Tell your doctor before using Lornestin:

- If you have severe liver problems (see **Do not take Lornestin** above);
- If you have a disease called Crohn's disease as it might interfere with the effectivity of Lornestin;
- If you have had depression with previous use of hormonal contraceptives. Mood changes and depression are side effects reported with the use of hormonal contraceptives including Lornestin.

Severe depression is associated with a higher risk of suicidal thoughts/behaviour (e.g., talking about suicide, withdrawing from social contact, having mood swings, being preoccupied with death or violence, feeling hopeless about a situation, increasing use of alcohol/drugs, doing self-destructive things, personality changes) and suicide. If you experience mood changes and depression, contact your doctor for advice.

If you have taken Lornestin, and your period is late by more than 5 days or you have it at the normal time, but it is abnormal or if you suspect pregnancy (feeling sick, nausea, vomiting, breast tenderness etc). you should tell your doctor.

After you have taken Lornestin, it is important that you make an appointment to see your doctor to ask him about regular methods of contraception that are suitable for you.

Other medicines and Lornestin

Always tell your healthcare professional if you are taking any other medicine. (This includes all complementary or traditional medicines).

Some medicines may prevent Lornestin from working effectively. If you have used any of the medicines below during the last 4 weeks, Lornestin 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). If this is not an option for you or if you are unable to see your doctor promptly, you can take a double dose of Lornestin.

Please inform your healthcare professional if you are currently taking any of the following medicines as it might reduce the efficacy of Lornestin:

- St. John's Wort (*Hypericum perforatum*);
- barbiturates, phenytoin, carbamazepine, primidone (for epilepsy);
- griseofulvin (for fungal infections);
- ritonavir (for HIV treatment);
- medication to treat diabetes (including insulin);
- any antibiotics (e.g., ampicillin, TB medication such as rifampicin, rifabutin);
- ciclosporin (used in organ transplants to prevent organ rejection). Lornestin may also affect how well ciclosporin works as levonorgestrel may cause toxic levels of ciclosporin.

Lornestin with food and/or drink

No data is available.

Pregnancy and breastfeeding

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 health care provider for advice before taking Lornestin.

Pregnancy

You should not take this medicine if you are already pregnant. If you do become pregnant even after taking this medicine, it is important that you see your doctor. There is no evidence that Lornestin will harm a baby that develops in your uterus/womb if you use Lornestin as described.

Breastfeeding

Levonorgestrel is excreted into your breast milk. Therefore, it is suggested that you take your tablet immediately after a breastfeeding and avoid breastfeeding at least 8 hours following Lornestin administration.

Fertility

Lornestin increases the possibility of menstruation disturbance which can sometimes lead to an earlier or later ovulation date resulting in modified fertility date. Although there are no fertility data in the long term, after treatment with Lornestin a rapid return to fertility is expected and therefore, regular contraception should be continued or initiated as soon as possible after Lornestin use.

Driving and using machines

It is not always possible to predict to what extent Lornestin may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which Lornestin affects them.

Lornestin contains lactose

Lornestin contains lactose, if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Lornestin

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

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

The tablet should be taken no later than 72 hours after unprotected sex.

Lornestin can be taken on any day of the menstrual cycle.

Take the tablet with a sufficient quantity of liquid (e.g., one glass of water).

If vomiting occurs within three to four (3 to 4) hours of taking your tablet, another tablet should be taken immediately.

After you have taken Lornestin, if you want to have sex, and are not using the contraceptive pill, you should use condoms or a cap plus spermicide until your next menstrual period. This is because Lornestin will not work if you have unprotected sex again before your next period is due.

You can continue to use your regular hormonal contraception.

Children

Lornestin is not recommended in children under the age of 16 years.

If you take more Lornestin than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Overdose may cause nausea, and vaginal bleeding.

There are no specific antidotes for Lornestin overdose and treatment provided will be symptomatic and supportive.

If you forget to take Lornestin

Do not take a double dose to make up for forgotten individual doses.

In case of unprotected sex more than 72 hours earlier, you may be pregnant and Lornestin should not be taken.

4. Possible side effects

Lornestin can have side effects.

Not all side effects reported for Lornestin are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Lornestin, please

inform your health care provider for advice.

Tell your doctor or health care provider if you notice any of the following:

Frequent side effects:

- Headache, dizziness.
- Nausea, lower abdominal pain, diarrhoea, vomiting.
- Bleeding not related to your monthly period, breast tenderness, delay in your monthly bleeding of more than 7 days, irregular menstruation.
- Fatigue (feeling tired).

Less frequent side effects:

- Skin rash, hives (red, itchy welts that result from a skin reaction called urticaria), itchy skin (pruritus).

Although most women will have their next period at the usual time, some will have a later, or earlier than normal period. If your period is late by more than 5 days or you have it at the normal time, but it is abnormal or if you suspect pregnancy (feeling sick, nausea, vomiting, breast tenderness etc), you should contact your doctor.

Side effects may include severe depression with a higher risk of suicidal thoughts/behaviour and suicide.

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

Reporting of side effects

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

5. How to store Lornestin

Store all medicines out of reach of children.

Store at or below 30 °C

Store the tablet in the original packaging until required for use.

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

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 Lornestin contains

- The active ingredient is levonorgestrel.
- The other ingredients are magnesium stearate, maize starch, potato starch, lactose monohydrate, silica colloidal anhydrous, talc.

What Lornestin looks like

Lornestin is white to off white, round bevel edged, flat faced tablets, debossed with “J06” on one side and plain on the other side.

Lornestin is packed in clear and transparent PVC blister pack with aluminium foil lidding, containing 1 tablet per blister in a cardboard carton.

Holder of Certificate of Registration

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