

PACKAGE LEAFLET: INFORMATION FOR THE USER

Emerres Una

1.5 mg Tablet

Levonorgestrel

Read all of this leaflet carefully before you start taking 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet:

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

1. What Emerres Una is and what it is used for

Emerres Una is commonly known as 'the morning after Pill'. It is used to reduce the chances of becoming pregnant after unprotected sex or failure of a contraceptive method.

Emerres Una contains the active ingredient levonorgestrel, which is a synthetic derivative of the naturally occurring female sex hormone and it is not fully understood how this medicine prevents pregnancy. It is thought to work by preventing ovulation and fertilisation and also by altering the lining of the womb, depending on which stage of the menstrual cycle the woman is at.

Emerres Una is not indicated for use before the first menstrual bleeding (menarche).

It is estimated that 84 per cent of pregnancies will be prevented if this morning-after Pill is taken within 72 hours of unprotected sex. The tablet is more effective at preventing pregnancy the earlier it is taken, so it is important to take it as soon as possible after unprotected sex, rather than delay to the third day.

2. What you need to know before you take Emerres Una

Do not take Emerres Una

- If you are allergic to levonorgestrel or any of the other ingredients of Emerres Una (see section 6).

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Emerres Una.

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

If any of the following applies to you, talk to your doctor before taking this medication as emergency contraception may not be suitable for you. Your doctor may prescribe another type of emergency contraception for you.

- If you are pregnant or think that you may already be pregnant. This medicine will not work if you are already pregnant. If you are already pregnant, Emerres Una cannot terminate pregnancy, as Emerres Una is not an "abortion Pill".

You may already be pregnant if:

- your period is more than 5 days late, or you have experienced unusual bleeding when your next period is due.
- you have had unprotected sex more than 72 hours ago, and since your last period.

The use of Emerres Una is not advised if:

- you have a disease of your small bowel (such as Crohn's disease) that inhibits the absorption of the drug.
- you have severe liver problems.
- you have a history of ectopic pregnancy (where the baby develops somewhere outside the womb).
- you have a history of salpingitis (inflammation of the Fallopian tubes).

A previous ectopic pregnancy and a previous infection of the fallopian tubes increase the risk of a new ectopic pregnancy.

Children and adolescents

If you are under 16, you must visit your doctor or family planning clinic to get emergency contraception.

If you are worried about sexually transmitted diseases

If you did not use a condom (or if it has been torn or slid down) during the intercourse, it might be possible that you have caught a sexually transmitted disease or the HIV virus.

This medicine will not protect you against sexually transmitted diseases, only condoms can do this. Ask your doctor, nurse, family planning clinic or pharmacist for advice if you are worried about this.

Other medicines and Emerres Una

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription or herbal medicines.

Some medicines may prevent Emerres Una from working effectively. If you have used any of the medicines below during the last 4 weeks, Emerres Una 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 Emerres Una:

- barbiturates and other medicines used to treat epilepsy (for example, primidone, phenytoin, and carbamazepine),
- medicines used to treat tuberculosis (for example, rifampicin, rifabutin),
- a treatment for HIV (ritonavir, efavirenz),
- a medicine used to treat fungal infections (griseofulvin),
- herbal remedies containing St John's wort (*Hypericum perforatum*).

Speak to your pharmacist or doctor if you need further advice on the correct dose for you.

Consult your doctor as soon as possible after taking the tablets for further advice on a reliable form of regular contraception and to exclude a pregnancy. (See section also 3 "How to take Emerres Una" for further advice).

Emerres Una may also affect how well other medicines work:

- a medicine called cyclosporin (suppresses the immune system).

How often can you use Emerres Una

You should only use Emerres Una in **emergencies** and not as a regular method of contraception. If Emerres Una is used more than once in a menstrual cycle it is more likely to upset your menstrual cycle (period). Emerres Una does not work as well as regular methods of contraception. Your doctor, practice nurse or family planning clinic can tell you about long-term methods of contraception which are more effective in preventing you from getting pregnant.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

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 Emerres Una will harm a baby that develops in your uterus/womb if you use Emerres Una as described.

Nevertheless, 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 develop severe abdominal pain after taking Emerres Una or if you have previously had an ectopic pregnancy, Fallopian tube surgery or pelvic inflammatory disease.

Breast-feeding

Very small amounts of the active ingredient of this medicine may appear in your breast milk. This is not thought to be harmful to the baby. If you are worried you can take your tablet immediately after a breast-feed and avoid nursing for at least 8 hours after taking Emerres Una. In this way you can reduce the amount of active ingredient your baby may take in with the breast milk.

Fertility

Emerres Una increases the chances of menstruation disturbances which can alter when your egg is released and therefore effect when you can become pregnant, however, there are no fertility data in the long term.

Driving and using machines

Emerres Una is unlikely to affect your ability to drive a car or use machines. However, if you feel tired or dizzy do not drive or operate machinery.

Emerres Una contains lactose

Emerres Una contains lactose. If you have been told by your doctor that you have an intolerance to sugars, contact your doctor before taking this medicine.

3. How to take Emerres Una

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

- Take the tablet as soon as possible, preferably within 12 hours, and no later than 72 hours (3 days) after you have had unprotected sex. Emerres Una can be taken at any time in your menstrual cycle assuming you are not already pregnant or think you may be pregnant. Do not chew but swallow the tablet whole with water. Do not delay taking the tablet. The tablet works best the sooner you take it after having unprotected sex. It can only prevent you becoming pregnant, if you take it within 72 hours of unprotected sex.

- If you are using one of the medicines that may prevent Emerres Una from working properly (see section above "Other medicines and Emerres Una") or if you have used one of these medicines in the past 4 weeks, Emerres Una may work less effectively 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 Emerres Una (i.e. 2 tablets taken together at the same time).

- If you are already using a regular method of contraception such as the contraceptive pill, you can continue to take this at your regular times.

If another unprotected intercourse takes place after the use of Emerres Una (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.

What to do if you are sick (vomit)

If you are sick (vomit) within three hours of taking the tablet, you should immediately take another tablet.

Once you have taken this medicine, talk to a pharmacist or doctor if your next period is more than 5 days late or you suspect you may be pregnant.

If you get any lower stomach pain or discomfort, talk to a doctor straight away.

After you have taken Emerres Una

After you have taken Emerres Una, 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 Emerres Una won't work if you have unprotected sex again, before your next period is due.

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After you have taken Emerres Una, you are advised to make an appointment to see your doctor about three weeks later, to make sure that Emerres Una has worked. If your period is more than 5 days late or is unusually light or unusually heavy, you should contact your doctor as soon as possible. If you do become pregnant even after taking this medicine, it is important that you 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.

If you continue to use regular hormonal contraception such as the contraceptive pill and you do not have a bleed in your pill-free period, see your doctor to make sure you are not pregnant.

Your next period after you took Emerres Una

After the use of Emerres Una, your period is usually normal and will start at the usual day; however sometimes, this will be a few days later or earlier. If your period starts more than 5 days later than expected, an 'abnormal' bleeding occurs at that time or if you think that you might be pregnant, you should check whether you are pregnant by a pregnancy test.

If you take more Emerres Una than you should

Although there have been no reports of serious harmful effects from taking too many tablets at once, you may feel sick, actually be sick (vomit), or have vaginal bleeding. You should ask your pharmacist, doctor, practice nurse or family planning clinic for advice, especially if you have been sick, as the tablet may not have worked properly.

4. Possible side effects

Like all medicines, Emerres Una can cause side effects, although not everybody gets them.

Very common (may affect more than 1 in 10 people):

- Feeling sick (nausea).
- You might have some irregular bleeding until your next period.
- You might have lower abdominal pain.
- Tiredness.
- Headache.

Common (may affect up to 1 in 10 people):

- Being sick (vomiting). If you are sick, read the section 'What to do if you are sick' (vomit).
- Your period might be different. Most women will have a normal period at the expected time, but some may have their period later or earlier than normal. You might also have some irregular bleeding or spotting until your next period. If your period is more than 5 days late or is unusually light or unusually heavy, you should contact your doctor as soon as possible.
- You might have tender breasts, diarrhoea, feel dizzy after taking this medicine.

Very rare effects (may affect up to 1 in 10000 people):

- Abdominal pain, rash, urticaria, pruritus, swelling of the face, pelvic pain, painful period.

If you get any of the side effects or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Emerres Una

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

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

This medicinal product does not require any special storage conditions.

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 protect the environment.

6. Contents of the pack and other information

What Emerres Una contains

- The active substance is levonorgestrel.
- The other ingredients are lactose monohydrate, povidone (E1201), maize starch, silica colloidal anhydrous (E551) and magnesium stearate (E572).

What Emerres Una looks like and contents of the pack

Emerres Una is a round, white to off-white, uncoated flat tablet debossed '145' on one side and plain on the other side. Each pack contains a blister with one tablet.

Marketing Authorisation Holder

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