

# Emerres

## PACKAGE LEAFLET: INFORMATION FOR THE USER

# Emerres

1.5 mg Tablet

## Levonorgestrel

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet:

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

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

Emerres 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 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 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

#### Do not take Emerres

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

#### Warnings and precautions

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

In all women, emergency contraception should be taken as soon as possible after unprotected intercourse. There is some evidence that Emerres may be less effective with increasing body weight or body mass index (BMI), but these data were limited and inconclusive. Therefore, Emerres 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 Emerres 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 cannot terminate pregnancy, as Emerres 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 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.

#### 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

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

- 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" for further advice).

Emerres may also affect how well other medicines work:

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

#### How often can you use Emerres

You should only use Emerres in emergencies and not as a regular method of contraception. If Emerres is used more than once in a menstrual cycle, it is less reliable and it is more likely to upset your menstrual cycle (period). Emerres 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 will harm a baby that develops in your uterus/womb if you use Emerres 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 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. In this way you can reduce the amount of active ingredient your baby may take in with the breast milk.

#### *Fertility*

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

#### Driving and using machines

Emerres 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 contains lactose

If you have been told by your doctor that you have intolerance to sugars, contact your doctor before taking this medicine.

### 3. How to take Emerres

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 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 from working properly (see section above "Other medicines and Emerres") or if you have used one of these medicines in the past 4 weeks, Emerres 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 (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 (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.

#### *Use in children and adolescents*

This medicine is not recommended for use in children. Very limited data is available in women under 16 years of age.

#### 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.

#### After you have taken Emerres

After you have taken Emerres, 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 will not work if you have unprotected sex again, before your next period is due.

After you have taken Emerres, you are advised to make an appointment to see your doctor about three weeks later, to make sure that Emerres 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

After the use of Emerres, 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 get any lower stomach pain or discomfort, talk to a doctor straight away.

#### If you take more Emerres 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 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):

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

If any of the side effects get serious 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](http://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

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 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 look like and contents of the pack

Emerres 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.

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