

Instructions for Pharmacists supplying Ezinelle as emergency contraception

Ezinelle (containing 1.5mg levonorgestrel) is an emergency contraceptive which can be used to prevent unintended pregnancy following unprotected sexual intercourse or contraceptive failure.

Ezinelle can be used at any time during the menstrual cycle unless menstrual bleeding is overdue.

After using emergency contraception it is recommended to use a local barrier method (e.g. condom, diaphragm, spermicide, cervical cap) until the next menstrual period starts. The use of Ezinelle does not contraindicate the continuation of regular hormonal contraception.

The following list of questions is designed to support you in determining whether Ezinelle is a suitable choice of emergency contraceptive for an individual patient following unprotected sexual intercourse or contraceptive failure. It is recommended that this checklist be used in conjunction with the full prescribing information for Ezinelle.

Question 1: Are you over 16?

Ezinelle is indicated for use in adults and adolescents >16 years of age, within 72 hours of unprotected sexual intercourse or failure of a contraceptive method. Ezinelle is not recommended for use by young women under 16 years of age without medical supervision.

Question 2: Is Ezinelle for your own use?

Ezinelle is only indicated for use by women over 16 years of age.

Question 3: Have you had unprotected sex within the last 72 hours (3 days)?

If 'No', refer to a surgery or family planning clinic.

Levonorgestrel prevents about 84% of expected pregnancies when taken within 72hrs of having unprotected sex. It will not prevent a pregnancy every time and is more effective if taken as soon as possible after unprotected sex. It is better taken within 12hrs rather than delay until the third day.

Question 4. Have you had unprotected sex earlier in this cycle?

Emergency contraception does not prevent a pregnancy in every instance. If there is uncertainty about the timing of the unprotected intercourse or if the woman has had unprotected intercourse more than 72 hours earlier in the same menstrual cycle, conception may have occurred. Treatment with Ezinelle following the second act of intercourse may therefore be ineffective in preventing pregnancy.

Question 5. Was your last period late, lighter/shorter or unusual in any way?

Emergency contraception does not prevent a pregnancy in every instance. If menstrual periods are delayed by more than 5 days or abnormal bleeding occurs at the expected date of menstrual periods or pregnancy is suspected for any other reason, pregnancy should be excluded.

Question 6. Have you already used Ezinelle (or other emergency contraception) since your last period?

Emergency contraception is an occasional method. It should not replace a regular contraceptive method. Repeated administration within a menstrual cycle is not advisable because of the possibility of disturbance of the cycle.

Ezinelle is not as effective as a conventional regular method of contraception and is suitable only as an emergency measure. Women who present for repeated courses of emergency contraception should be advised to consider long-term methods of contraception.

Question 7: Are you currently taking any other medicines, including herbal remedies (e.g. St John's wort)

The metabolism of levonorgestrel is enhanced by concomitant use of liver enzyme inducers. Drugs suspected of having the capacity to reduce the efficacy of levonorgestrel containing medication include barbiturates (including primidone), phenytoin, carbamazepine, herbal medicines containing *Hypericum perforatum* (St. John's wort), rifampicin, ritonavir, rifabutin, griseofulvin and efavirenz.

Medicines containing levonorgestrel may increase the risk of ciclosporin toxicity due to possible inhibition of ciclosporin metabolism.

Question 8: Do you suffer from bowel disease (e.g. Crohn's Disease) or liver problems?

Severe malabsorption syndromes, such as Crohn's disease, might impair the efficacy of Ezinelle.

Ezinelle is not recommended in patients with severe liver disease.

Question 9: Have you ever had an allergy to levonorgestrel or any of the other ingredients in Ezinelle?

Ezinelle is contraindicated if the patient has hypersensitivity to the active substance or to any of the ingredients.

Ezinelle tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Call for healthcare professionals for reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to Mylan. Should you have wish to report an adverse event or have any questions, please call Medical Information at Mylan UK Ltd. Tel: +44 1707853000 (24 hours) or send an e-mail to info@mylan.co.uk.

Adverse events can also be reported via the Yellow Card System (www.mhra.gov.uk/yellowcard).

Please refer to the full Summary of product Characteristics (SmPC) for more information.

Patient Questionnaire

Private and Confidential

To be completed by the patient

Date:

Answer as many questions as possible by ticking the boxes and completing the required information.

If you get stuck on a question, leave it blank and ask the pharmacist to help you

1. Are you over 16?

Yes

No

(If not, check with pharmacist before answering any more questions.)

Pharmacists are not allowed to sell Ezinelle to women under 16. But you can obtain it under medical supervision from your doctor, practice nurse or family planning adviser.

2. Is Ezinelle for your own use?

Yes

No

3. Have you had unprotected sex within the last 72 hours (3 days)?

Yes

No

4. Have you had unprotected sex earlier in this cycle?

Yes

No

5. Was your last period late, lighter/shorter or unusual in any way?

Yes

No

6. Have you already used Ezinelle (or other emergency contraception) since your last period?

Yes

No

7. Are you currently taking any other medicines, including herbal remedies (e.g. St John's wort)

Yes

No

Please write down the name(s) of any medicines you are currently taking. Remember to include all pills, tablets, inhalers and syrups.

8. Do you suffer from bowel disease (e.g. Crohn's Disease) or liver problems?

Yes

No

9. Have you ever had an allergy to levonorgestrel or any of the other ingredients in Ezinelle?

(Levonorgestrel is a hormone commonly used in the combined contraceptive pill and is the active ingredient in Ezinelle)

Yes

No

Ezinelle should not replace regular, long-term contraception. Advice on contraception is available free from your GP, Family Planning Clinic or NHS Walk-in Centre. Always read the patient information leaflet. Contains levonorgestrel. Not 100% effective.

Advice Leaflet for women taking Ezinelle

Advice for women taking Ezinelle

1. Ezinelle should only be used in an emergency

Levonorgestrel emergency contraception works best when you take it as soon as possible after unprotected sex. It is 84% effective within 72 hours of having unprotected sex. Ezinelle does not work as well as regular methods of contraception and will not always stop a pregnancy.

2. Timing of the tablet is very important

In each pack of Ezinelle, there is one tablet. This should be taken as soon as possible after unprotected sex.

3. Possible side effects of Ezinelle

You might feel sick, have tender breasts, headaches, tummy pain, diarrhoea, feel dizzy or tired after taking Ezinelle. These symptoms should get better within a few days. If you are worried about the way you are feeling, talk to your doctor or pharmacist.

You may actually be sick (vomit) after taking Ezinelle. 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.

If you are sick (vomit) within three hours of taking the tablet, you should take another tablet. You will need to contact your pharmacist, doctor, practice nurse or family planning clinic immediately for one more tablet.

4. Using contraception after taking Ezinelle

Ezinelle will not protect you against pregnancy for the rest of your menstrual cycle.

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

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.

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.

You may wish to make an appointment to see your doctor after taking Ezinelle to discuss regular long-term methods of contraception, which are more effective in preventing you from getting pregnant.

5. Possible changes to your next period

After taking Ezinelle, most women will have a normal period at the expected time, but some may have their period a few days earlier or later than normal. If your next period is different from normal or more than 5 days late, make an appointment to see your doctor as soon as possible. Spotting or bleeding may occur before your next period after taking Ezinelle.

6. How often can I take Ezinelle?

You should only use Ezinelle in emergencies and not as a regular method of contraception. If Ezinelle is used more than once in a menstrual cycle, it is more likely to upset your menstrual cycle (period).

Ezinelle 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.

7. How do I know if Ezinelle has worked?

If you are not pregnant you should have your next period as usual, although it may be a little early or a little late. If your period is more than 5 days late or unusually light or unusually heavy contact your doctor as soon as possible.

Ezinelle should not replace regular, long-term contraception. Advice on contraception is available free from your GP, Family Planning Clinic or NHS Walk-in Centre. Always read the patient information leaflet. Contains levonorgestrel. Not 100% effective.