Package leaflet: Information for the user

Escapelle 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 take this medicine exactly as described in this leaflet or as your doctor or pharmacist 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Escapelle is and what it is used for

Escapelle is an emergency contraceptive that can be used within 72 hours (3 days) of unprotected sex or if your usual contraceptive method has failed.
It is about the following cases:
- No contraception was used during the sexual intercourse.
- The contraception measure was used incorrectly, for example as if a condom was penetrated, slipped away or used in a wrong way, if vaginal pessary or diaphragm changed position, burst, was broken or taken out ahead of time, in the case of a failed interruption during coitus interruptus (e.g. sperm ejaculated in vagina or on external genitalia).

Escapelle contains a synthetic hormone like active substance called levonorgestrel. It prevents pregnancy in 99% of situations when you take it within 72 hours of having unprotected sex. It will not prevent a pregnancy every time and is more effective if you take it as soon as possible after unprotected sex. It is better to take it within 12 hours rather than delay until the third day.

Escapelle is thought to work by:
- stopping your ovaries from releasing an egg.
- preventing sperm from fertilising any egg you may have already released.

Escapelle 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 another unprotected intercourse takes place after the use of Escapelle (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.

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

2. What you need to know before you take Escapelle

Do not useEscapelle
- if you are allergic to levonorgestrel or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
If any of the following applies to you, talk to your doctor before taking Escapelle 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, Escapelle cannot terminate pregnancy, so Escapelle 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 Escapelle 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 or previous infection of the fallopian tubes increase the risk of a new ectopic pregnancy.

Your doctor may decide that Escapelle is not suitable for you, or that another type of emergency contraception would be better for you.

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

Children and adolescents
Escapelle is not indicated for use before the first menstrual bleeding (menarche).

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

Some medicines may prevent Escapelle from working effectively. If you have used any of the medicines below during the last 4 weeks, Escapelle 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 Escapelle:
- 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 also section 3 "How to take Escapelle" for further advice).

Escapelle may also affect how well other medicines work:
- a medicine called cyclosporin (suppresses the immune system).

How often can you use Escapelle
You should only use Escapelle *in emergencies* and not as a regular method of contraception. If Escapelle is used more than once in a menstrual cycle, it is less reliable and it is more likely to upset your menstrual cycle (period).
Escapelle 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 this 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 Escapelle will harm a baby that develops in your uterus/womb if you use Escapelle 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 Escapelle or if you have previously had an ectopic pregnancy, fallopian tube surgery or pelvic inflammatory disease.

Breast-feeding
The active ingredient of this medicine is excreted into your breast milk. Therefore, it is suggested that you take your tablet immediately after a breast-feeding and avoid nursing at least 8 hours following levonorgestrel administration then drain your milk with a breast pump for 8 hours following tablet taking. In this way you are taking your tablet well before the next feed and reducing the amount of active ingredient your baby may take in with the breast milk.

Fertility
Escapelle 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 Escapelle a rapid return to fertility is expected.

Driving and using machines
Your Escapelle tablet 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.

Escapelle contains lactose
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 take Escapelle

Always use this medicine exactly as described in this leaflet or as your doctor or 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 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.

- Escapelle 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.
- If you are using one of the medicines that may prevent Escapelle from working properly (see section above "Other medicines and Escapelle") or if you have used one of these medicines in the past 4 weeks, Escapelle 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 Escapelle (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 Escapelle (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. You will need to contact your pharmacist, doctor, practice nurse or family planning clinic immediately for one more tablet.

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

After you have taken Escapelle, you are advised to make an appointment to see your doctor about three weeks later, to make sure that Escapelle 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 Escapelle
After the use of Escapelle, 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 Escapelle 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.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common side effects (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 side effects (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 side effects (may affect up to 1 in 10,000 people):
- Rash, urticaria, pruritus, swelling of the face, pelvic pain, painful period.

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 national reporting system ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Escapelle

Store out of the sight and reach of children.

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

Store in the original packaging in order to protect from light.

Do not dispose of the drug in the sewer or household waste. Ask your pharmacist how to throw away medicines that you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Escapelle contains

- The active ingredient is levonorgestrel. **Each tablet contains 1.5 mg of levonorgestrel.**
- Other ingredients are potato starch, corn starch, colloidal silica, magnesium stearate, talc, lactose monohydrate.

What Escapelle looks like and contents of the pack

Almost white, flat tablet, with an oblique edge 8 mm in diameter and an indent "G00" on one side. Escapelle is packed in an aluminium/PVC blister (1 tablet) and a cardboard box.

Marketing Authorisation Holder and Manufacturer

Gedeon Richter Plc.
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For more information about this medicine, please contact the local representative office of the Marketing Authorisation Holder:
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