



**Escapelle 1500 microgram tablet
(levonorgestrel)
Brochure for patients**

For further information and additional details on Escapelle, please see the Patient Information Leaflet (PIL).

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For further information and additional details on Escapelle, please see the Patient Information Leaflet (PIL).

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I Definition

I.1. What is emergency contraception?

Emergency contraception (EC), also known as postcoital contraception refers to contraceptive methods that can be used after unprotected or inadequately protected act of sexual intercourse. These methods including emergency contraceptive pills (ECPs) as well as insertion of a copper intrauterine device can give you an additional opportunity to prevent unintended pregnancy following unprotected sexual intercourse (UPSI) or failure of a contraceptive method (e.g. a split condom). It offers women the opportunity to reduce the risk of unplanned pregnancy after an episode of unprotected intercourse (UPSI).

I.2. What is the difference between emergency contraception, the “morning after pill” and the “day after pill”?

There is no difference between these terms. They all refer to the emergency contraceptive pill. However, the preferred term is emergency contraception instead of the more casually ‘morning after pill’ as using the latter could be misleading. You should take this pill as soon as possible after the UPSI instead of waiting for the next day as its efficacy appears to decline with time of start of treatment after intercourse.

I.3. Why should I use Escapelle emergency contraception only in case of emergency?

This medicine is intended for occasional use only. It should not be used on a regular basis, or as a substitute for long-term contraception.

Emergency contraception (EC) is not a substitute for effective regular contraception.

Escapelle 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. Escapelle does not work as well as regular methods of contraception and will not always stop a pregnancy.

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

II Indication, Posology

II.1. In which cases is emergency contraception likely to be needed?

- If no contraception was used during the sexual intercourse.
- The contraception measure was used incorrectly, for example:
 - if the condom broke, slipped off or was used in a wrong way,
 - regular contraceptive was started 2 days later than it was scheduled,
 - more than 2 tablets of regular contraceptive were missed in the first week,
 - combined pill has been missed by more than 12 hours late in the first week,
 - if vaginal pessary or diaphragm changed position, burst, was broken or was removed ahead of time,
 - in the case of a failed withdrawal during coitus interruptus (e.g. sperm ejaculated in vagina or on external genitalia).

For further information and additional details on Escapelle, please see the Patient Information Leaflet (PIL).

II.2. Is there an age limit of taking Escapelle emergency contraception pill?

Escapelle is not indicated for use before the first menstrual bleeding (menarche). Thus Escapelle can be given to women under 16 years provided that she is judicious according to the health care professionals' assessment (usually pharmacists).

II.3. When should I take it under medical supervision only?

- in any doubt about existing pregnancy or risk factors
 - if the unprotected intercourse has taken place more than 72 hours earlier / you have had unprotected sex more than 72 hours ago, and since your last period
 - your period is more than 5 days late, or you have experienced unusual bleeding when your next period is due
- if she takes other medication (including herbal remedies) which can interact with Escapelle
- if she suffers from bowel disease or severe liver disease / you have a disease of your small bowel (such as Crohn's disease) that inhibits the absorption of the drug
- if she has an allergy to Escapelle or any ingredients of the product / if you are allergic to levonorgestrel or any of the other ingredients of this medicine (listed in the Package Leaflet)
- 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)

If any of the above 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.

II.4. How to take Escapelle pill?

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

Take one tablet as soon as possible, preferably within 12 and no later than 72 hours after unprotected sex or failure of contraception. 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 is better to take it within 12 hours rather than delay until the third day.

The whole tablet (*in case of 1.5 mg*) should be swallowed with water. It should be taken as soon as possible following unprotected intercourse or failure of a contraceptive method, but no later than three days (72 hours) of having unprotected sex. It can be used at any time during the menstrual cycle unless menstrual bleeding is overdue.

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

For further information and additional details on Escapelle, please see the Patient Information Leaflet (PIL).

II.5. Is physical examination or any lab tests needed to get emergency contraception?

No. However, if there is uncertainty about the timing of the unprotected intercourse or if you have had unprotected intercourse more than 72 hours earlier in the same menstrual cycle, there is a risk of pregnancy. In such case pregnancy testing prior to EC administration should be considered.

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 before taking Escapelle.

II.6. If you are pregnant

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

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.

II.7. If you are breastfeeding

If you are breast-feeding, ask your doctor or pharmacist for advice before taking any medicine.

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 for at least 8 hours following Escapelle 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.

II.8. How often can I use Escapelle emergency contraceptive pills?

This medicine should only be used for emergencies and not as a regular method of contraception, because it is not as reliable as regular methods of contraception and offers no protection against sexually transmitted diseases. It is also not recommended to take this medicine more than once in a monthly cycle it can disturb your period. To discuss long-term methods of contraception, which may be more effective, talk to your doctor, nurse or family planning clinic. Your pharmacist may also be able to help answer any questions you have about long-term methods of contraception.

II.9. What happens if I take Escapelle more than once in a cycle?

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).

For further information and additional details on Escapelle, please see the Patient Information Leaflet (PIL).

Repeated administration within a menstrual cycle is not advisable due to increased risk of side effects, such as menstrual irregularities, although Escapelle frequent use poses no known health risks.

Escapelle can be used more than once in the same cycle if this is indicated by further UPSI.

On the other hand, emergency contraceptives have higher possibility of failure compared to regular contraceptives; therefore, they are suitable only for occasional use after UPSI.

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.

II.10. Can food or drink (i.e. alcohol) affect Escapelle?

The absorption of the drug is not affected significantly if it is taken before or after the meal, therefore Escapelle can be taken anytime irrespective to the time of meals.

Data is not available as food-drug interactions were not investigated in the clinical trials. Related information is neither included in the SmPCs of Levonorgestrel containing COCs. Relevant data cannot be found in the scientific literature either.

II.11. What to do if I vomit after taking the pill?

If you are sick within 3 hours of taking the tablet, you will need to take another tablet. Talk to our pharmacist, doctor, nurse or family planning clinic immediately for advice and to obtain another tablet.

II.12. If I have several unprotected intercourses within 72 hours of taking Escapelle will I still be protected against unwanted pregnancy?

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.

After you have taken Escapelle, 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.

If another unprotected intercourse takes place after the use of Escapelle, the tablet will not provide contraceptive cover and there is the risk of pregnancy again. Ongoing contraception will need to be used or refraining from sex to avoid further risk of pregnancy. 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. Furthermore, use of Escapelle does not contraindicate the continuation of regular hormonal contraception. If the woman is already using regular oral contraceptive, she can continue to take this at the regular times. She also should be advised to use additional contraceptive precautions for 7 days (2 days for POP, 9 days for Qlaira).

The general advice is to use barrier contraception (such as condom or diaphragm) after using Escapelle or consult a doctor for a long-term contraceptive method.

For further information and additional details on Escapelle, please see the Patient Information Leaflet (PIL).

Women should be advised that Escapelle will not provide contraceptive cover for subsequent acts of UPSI and that they will need to use contraception or refrain from sex to avoid further risk of pregnancy.

II.13. When do I need follow-up care after using Escapelle?

- if ectopic pregnancy can be suspected after the use of Escapelle
- asking for regular contraception
- you should seek medical advice if you vomit within 3 hours of taking Escapelle
- make a medical appointment to initiate or adopt a method of regular contraception
- if your next menstrual period is delayed with more than five days or abnormal bleeding occurs, you should contact your doctor as soon as possible
- if pregnancy occurs after Escapelle intake, it is important that you see your doctor as the possibility of an ectopic pregnancy may be considered

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 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. 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.

III Concomitant disease, concomitant drug use

III.1. Are you under treatment for epilepsy, TB or HIV?

Some medicines may prevent Escapelle from working effectively. 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, especially:

- 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*)

If you have used any of the medicines above 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.

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

III.2. Does St John's Wort interact with Escapelle?

A drug interaction is a situation in which a medicine affects the activity of another drug when both are administered together. Herbal remedies containing St John's Wort (*Hypericum*

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perforatum) interact with Escapelle. These remedies can reduce the efficacy of emergency hormonal contraceptives. Therefore, if you need emergency contraception whilst using St. John's Wort or have used during the last 28 days, you should use a non-hormonal EC, i.e. Cu-IUD. Taking a double dose of Escapelle (i.e. 3 mg within 72 hours after the UPSI) is an option if you are unable or unwilling to use a Cu-IUD.

III.3. Can Escapelle affect other medicinal products?

Escapelle may increase the risk of cyclosporin toxicity due to possible inhibition of cyclosporin metabolism. / may also affect how well other medicines work: a medicine called cyclosporin (suppresses the immune system-given after transplant surgery, or for psoriasis or rheumatism).

If you are unsure about interactions with any other medicines, talk to your doctor or pharmacist. This includes medicines prescribed by your doctor or medicines you have bought for yourself including herbal and homeopathic remedies.

III.4. How do I start or continue using a contraceptive method after taking Escapelle?

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

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

If you are already using a regular method of hormonal contraception (such as the contraceptive pill), continue using these as normal at your regular times, as well as using barrier methods of contraception until your next period.

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.

IV Efficacy

IV.1. How does morning after pill work?

The precise mode of action of Escapelle is not known. At the recommended regimen, Escapelle works mainly by preventing or delaying ovulation. Research also indicates ovulation interruption is not the only way this tablet works. Additional mechanisms of action include preventing fertilization of an egg by affecting the cervical mucus or the ability of sperm to bind to the egg. Escapelle is not effective once the process of implantation has begun. It is not an "abortion pill" as it does not interrupt a pregnancy.

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.

For further information and additional details on Escapelle, please see the Patient Information Leaflet (PIL).

IV.2. How does EC differ from abortion?

Escapelle is not abortive and should not be used during an existing pregnancy

If you are already pregnant, Escapelle cannot terminate pregnancy, so Escapelle is not an “abortion pill”.

EC is not the same as early medical abortion. Escapelle can only prevent pregnancy before the implantation of fertilised egg. It is not effective once the process of implantation has begun.

Escapelle is not an ‘abortion pill’ as it cannot terminate pregnancy. Evidence suggests that Escapelle does not interrupt an established pregnancy or harm a developing embryo.

IV.3. How effective is it?

Emergency contraception can be very effective especially if the emergency contraceptive pill is taken soon after unprotected sex. Efficacy appears to decline with time after intercourse.

Escapelle prevents about 85% of expected pregnancies when the woman takes it within 72 hours of having unprotected sex. However, after this time period uncertainty occurs whether this drug is still able to prevent pregnancy. The medicine may not work properly if the timing of the unprotected sex is uncertain or if the unprotected intercourse happened more than 72 hours ago. It will not prevent a pregnancy every time and is more effective if it taken as soon as possible after unprotected sex.

The pregnancy rate was 1.1 %^a (11/976^b) in an earlier clinical study where 0.75 mg of levonorgestrel was taken as two 0.75 mg doses with a 12-hour interval. Pregnancy rates appeared to increase with time of start of treatment after intercourse as follows:^a

- within 24 hours: 0.4 % (2 pregnancies among 450 women)
- between 25 and 48 hours: 1.2 % (4 pregnancies among 338 women)
- between 49 and 72 hours: 2.7 % (5 pregnancies among 187 women)¹

Results from another randomised, double-blind clinical study showed 1.34 %^c (16/1198) pregnancy rate with two 0.75 mg tablets of Escapelle taken at the same time (and within 72 hours of unprotected sex) compared with 1.69 %^c (20/11832) when two 0.75 mg tablets were taken 12 hours apart.²

IV.4. Should I wait 72 hours to take Escapelle emergency contraception pill?

Escapelle is an emergency contraceptive that can be used within 72 hours (3 days) of unprotected sex or if the patient’s usual contraceptive method has failed. The time frame is exceptionally important in the case of post coital contraception. Escapelle should be taken as soon as possible, preferably within 12 hours, and no later than 72 hours (3 days) after sexual intercourse.

^a LNG EC prevented 85 % of expected pregnancies; 95 % within 24 hours, 85 % 24-48 hours, 58 % if started between 48 and 72 hours.¹

^b 1 woman did not have information on coitus-to-treatment interval

^c LNG EC prevented 84 % of expected pregnancies when 2x0.75 mg tablets were taken at the same time; prevented fraction was 79 % when two 0.75 mg tablets were taken 12 hours apart.²

For further information and additional details on Escapelle, please see the Patient Information Leaflet (PIL).

IV.5. Does body weight influence the efficacy of Escapelle?

There is some evidence that Escapelle may be less effective with increasing body weight, but these data were limited and inconclusive. Therefore Escapelle is still recommended for all women regardless of their weight.

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.

V Safety

V.1. How safe is it?

Levonorgestrel containing emergency contraception pills are very safe and do not interrupt an established pregnancy or harm future fertility. Side-effects, generally similar to those experienced by women using oral contraceptive pills, are uncommon and generally mild. Systematic review of safety data for adverse events relating to use of EC by healthy women concludes that such events are rare.

V.2. What are the possible side effects of taking Escapelle pill?

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

Headache, nausea and altered bleeding patterns are side effects very common to Escapelle use and have been reported in around 10 % of users. After taking Escapelle, bleeding patterns may be temporarily disturbed, but most women will have their next menstrual period within 7 days of the expected time. Irregular menstruation and delay of menses more than 7 days are among the common side effects. However, in case of any serious or unusual event (e.g. more than 5 days delay of the next period) immediate gynaecologic examination and pregnancy test should be done.

Other reported side effects of Escapelle include lower abdominal pain, fatigue, breast tenderness, dizziness, diarrhoea and vomiting. If a woman vomits within three hours of taking Escapelle she should take a further dose as soon as possible.

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

You might feel sick, have tender breasts, headaches, tummy pain, diarrhoea, feel dizzy or tired after taking Escapelle. 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 Escapelle. You should ask your pharmacist, doctor, practice nurse or family planning clinic for advice, especially if you have vomited, 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.

For further information and additional details on Escapelle, please see the Patient Information Leaflet (PIL).

V.3. Does the pill change my period?

After the use of Escapelle the period is usually normal and will start at the usual day; however sometimes it might be different. Most women will have a normal period on the expected date, but some may have their period later or earlier than normal. They might also have some irregular bleeding or spotting until the next period. If your period starts more than 5 days later than expected, an ‘abnormal’ bleeding occurs at the time or pregnancy are suspected, you should contact your doctor as soon as possible, to check whether you are pregnant. If you do become pregnant even after taking Escapelle, it is important to see your doctor.

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 performing pregnancy test.

After taking Escapelle 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 Escapelle.

V.4. When do you have to turn to your doctor?

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.

V.5. Does Escapelle protect against sexually transmitted diseases?

This medicine will not protect you against sexually transmitted diseases, only condoms can help do this. If you are worried about any sexually transmitted disease, talk to your pharmacist, doctor, nurse or family planning clinic for advice.

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.

V.6. Can Escapelle harm a foetus or cause birth defects if taken by a woman who is already pregnant?

There is no evidence that Escapelle will harm a baby that develops in your uterus/womb if you use Escapelle as described.

Although there is no evidence that Escapelle could cause harm to either a pregnant woman or her foetus if pregnancy occurs despite use of Escapelle, the tablet should not be taken in case of a confirmed pregnancy. Escapelle can prevent unintended pregnancy but does not interrupt one. However, it is important to seek medical examination in order to exclude ectopic pregnancy.

V.7. Can I take Escapelle if I have previously had an ectopic pregnancy?

An ectopic pregnancy is a complication of pregnancy in which the embryo implants and develops outside the cavity of the woman’s womb (uterus). If an ectopic pregnancy is left unnoticed and untreated, the growing embryo might obstruct certain vessels that surround it,

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accidental bleeding and tissue damage may occur which can result in life-threatening internal bleeding of the mother and risks the possibility of latter child-bearing. For this reason, if pregnancy occurs after treatment with Escapelle the possibility of an ectopic pregnancy should be considered. The absolute risk of ectopic pregnancy is likely to be low, as Escapelle prevents ovulation and fertilisation too.

Escapelle is not recommended for patients who are at risk of ectopic pregnancy, such as patients with previous history of salpingitis (inflammation of the Fallopian tubes), Fallopian tube surgery or of ectopic pregnancy.

If the woman develops severe abdominal pain after taking Escapelle it is important to rule out an ectopic pregnancy, especially if the patient has an increased risk for an ectopic pregnancy.

References:

¹ Randomised controlled trial of levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for emergency contraception. Task Force on Postovulatory Methods of Fertility Regulation: WHO. Lancet 1998, 352:428-433.

² Von Hertzen H, Piaggio G, Ding J, Chen J, et al. for the WHO Research Group on Postovulatory Methods of Fertility Regulation. Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: a WHO multicentre randomised trial. Lancet 2002, 360:1803-1810.

Suspected adverse reactions and medication errors should be reported.

Report forms can be downloaded from:

www.medicinesauthority.gov.mt/adrportal

and sent to:

E: postlicensing.medicinesauthority@gov.mt or

E: pv@alfredgera.com

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