

ESCAPELLE[®] TABLET

Levonorgestrel (1.5 mg)

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What *Escapelle* 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.

How *Escapelle* works

Escapelle contains a synthetic hormone called levonorgestrel. *Escapelle* prevents about 84% of expected pregnancies when you take it within 72 hours of having unprotected sex. It will not prevent a pregnancy every time. If another unprotected sex 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 thought to work by:

- stopping your ovaries from releasing an egg;
- preventing sperm from fertilising any egg you may have already released.

Before you use *Escapelle*

- When you must not use it

If you are hypersensitive to levonorgestrel or any of the ingredients of this medicine.

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

Pregnancy and lactation

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 *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.

Lactation

Very small amount of the active ingredient of this medicine may appear in your breast milk. This is not thought to be harmful to the baby, but if you are worried, you can take your tablet immediately after a breast-feeding and avoid nursing at least 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. These changes can result in modified fertility date, however, the effects of *Escapelle* on fertility over long term is not known.

- Before you start use it

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, because *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.

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 medicine
- if you have severe liver problems

- if you have a history of ectopic pregnancy (where the baby develops somewhere outside the womb)
- if you have ever had a disease called salpingitis (inflammation of the Fallopian tubes).

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.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy from a pharmacy, supermarket or health food shop without a prescription.

Some medicines may prevent *Escapelle* from working effectively:

- 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 (for example, ritonavir, efavirenz)
- a medicine used to treat fungal infections (griseofulvin)
- herbal remedies containing St John's Wort (*Hypericum perforatum*).

If you are using one of these medicines, your doctor may prescribe you another type of emergency contraceptive, or your doctor may advise you to take a double dose of *Escapelle* (see section "How to use *Escapelle* – How much to use").

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

Escapelle may also affect how well other medicines work

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

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

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Consult your doctor or pharmacist before using *Escapelle* if you use any of the above-mentioned medicines.

How to use *Escapelle*

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- 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. *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 "Taking other medicines") 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, contact your doctor promptly to take a double dose of *Escapelle* (i.e. 2 tablets taken together at the same time).

What to do if you are sick (vomit)

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.

- When to use it

Use as directed by your doctor or pharmacist.

In all women, emergency contraception should be taken as soon as possible after unprotected intercourse. Do not delay taking the tablet.

- How long to use it

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.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. 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.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

After you have taken Escapelle

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. (See section "How *Escapelle* works".)

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, pregnancy should be excluded.

Consult your doctor as soon as possible after taking the tablet for further advice on a reliable, regular, long-term method of contraception and 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.

- Things you must not do

Do not take any new medicines without consulting your doctor. Do not give *Escapelle* to anyone else.

- Things to be careful of

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.

Escapelle contains lactose

Each *Escapelle* tablet also contains 142.5 mg lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

Side effects

Like all medicines, *Escapelle* can cause side effects, although not everybody gets them.

Very common side effects:

- Feeling sick (nausea)
- You might have bleeding not related to your period
- You might have lower abdominal pain
- Tiredness
- Headache

Common side effects:

- Being sick (vomiting). If you are sick, read the section 'What to do if you are sick (vomit)'.
- Bleeding patterns may be temporarily disturbed, but most women will have their next menstrual period within 5-7 days of the expected time. If the next menstrual period is more than 5 days overdue pregnancy should be excluded.
- You might have tender breasts, diarrhoea, feel dizzy after taking this medicine.

Very rare side effects:

- Rash, hives, itching, swelling of the face, pelvic pain, painful period, abdominal pain.

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of *Escapelle*

- Storage

Keep out of the reach and sight of children.

Store below 30°C in the original package in order to protect from light.

Do not store any medicine in the bathroom, or near a sink, or on a window sill.

Do not leave it in the car especially on hot days. Heat and dampness can destroy medicines.

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

Nature and contents of container

One carton of *Escapelle* contains one blister of one tablet.

- Disposal

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Almost white, flat, rimmed tablets of about 8 mm diameter, with an impressed mark of 'GOO' on one side.

- Ingredients

- Active ingredient(s)

Levonorgestrel

- Inactive ingredients

Potato starch, maize starch, colloidal anhydrous silica, magnesium stearate, talc, lactose monohydrate.

- MAL number:

MAL06030792AZ

Manufacturer

Gedeon Richter Plc.

H-1103 Budapest

Gyömrői út 19-21.

Hungary

Product Registration Holder

Pahang Pharmacy Sdn. Bhd

Lot 5979, Jalan Teratai,

5 ½ Miles off Jalan Meru,

41050 Klang, Selangor,

Malaysia

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26/08/2021

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