PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S2

ESCAPELLE

Levonorgestrel

Tablet

Contains sugar

Please read this leaflet carefully before taking ESCAPELLE tablets.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ESCAPELLE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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 tablet contains a synthetic luteal hormone-like active substance, levonorgestrel.

ESCAPELLE is an oral emergency contraceptive. It may help to prevent a pregnancy if taken within 72 hours of unprotected sexual intercourse or failure of a contraceptive method or the used method of contraception was not considered as safe.

It has been estimated that ESCAPELLE prevents 84 % of expected pregnancies when administered within 72 hours after unprotected intercourse. If you are uncertain about the timing of unprotected

intercourse or if you have had unprotected sex more than 72 hours earlier in the same menstrual cycle, conception may have occurred. Treatment with ESCAPELLE following the second act of intercourse may therefore be ineffective in preventing pregnancy.

ESCAPELLE is not as effective as a conventional regular method of contraception. If you think you need repeated courses of emergency contraception you should consider long-term methods of contraception.

2. What you need to know before you take Escapelle

Do not take ESCAPELLE:

- If you are hypersensitive (allergic) to levonorgestrel or any of the other ingredients of ESCAPELLE.
- If you suffer from severe liver impairment.
- If you are pregnant.
- You have depression, which is not well controlled with treatment.
- You have had depression with previous use of hormonal contraceptives.

Take special care with ESCAPELLE:

If you become pregnant even after taking this medicine, it is important to see your doctor. There is no evidence that ESCAPELLE will harm a baby that develops in your womb but 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 have severe abdominal pain or if you have previously had an ectopic pregnancy, fallopian tube surgery or pelvic inflammatory disease.

Warnings and precautions

Tell your doctor before using Escapelle:

- That you are on treatment for depression.
- That you have had depression with previous use of hormonal contraceptives.
- That you have a substance abuse problem.
- You have underlying psychiatric disorder such as post-traumatic stress disorder or bipolar disorder.
- That you have a family history of mental disorders.
- That you have a history of physical or sexual abuse.

Hormonal contraceptives including Escapelle, may cause mood changes and depression, which may be severe.

Severe depression is associated with a higher risk of suicidal thoughts/behavior (e.g. talking about suicide, withdrawing from social contact, having mood swings, being preoccupied with death or violence, feeling hopeless about a situation, increasing use of alcohol/drugs, doing self-destructive things, personality changes) and suicide. If you experience mood changes and depression contact your doctor for advice.

If you have taken **ESCAPELLE,** and your period is late by more than 5 days or you have it at the normal time but it is abnormal or if you suspect pregnancy (feeling sick, nausea, vomiting, breast tenderness etc). you should tell your doctor.

Tell your doctor:

- If you have severe liver dysfunction.
- If you suffer from Crohn's disease. This disease may impair the efficacy of ESCAPELLE.

Do not use ESCAPELLE repeatedly within a menstrual cycle; it may disturb your cycle. After you have taken ESCAPELLE, it is important that you make an appointment to see your doctor to ask him about regular methods of contraception that are suitable for you.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

You should not take ESCAPELLE if you are pregnant; ESCAPELLE will not interrupt the pregnancy.

In case of failure of this emergency contraception due to an already existing pregnancy, limited data from epidemiological studies indicate no adverse effects of levonorgestrel (active ingredient) on the foetus.

The active ingredient of ESCAPELLE is secreted into breast milk. If you are breast-feeding take ESCAPELLE tablet after feeding.

Driving and using machinery:

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

Important information about some of the ingredients of ESCAPELLE:

In case of lactose (milk-sugar) intolerance you should take into account that each ESCAPELLE tablet contains 142,5 mg lactose monohydrate.

Using other medicines with ESCAPELLE:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Tell your doctor if you are using herbal medicines containing Hypericum perforatum (St. John's Wort), any antibiotics (e.g. ampicillin, TB medication), or cyclosporine.

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:

Tell your doctor if you are using medicines to treat:

- Epilepsy (e.g. phenytoin, carbamazepine, primidone)
- Fungal infections (e.g. griseofulvin, ketoconazole, itraconazole)
- Viral infections (e.g. ritonavir)
- Diabetes
- Cyclosporine

3. HOW TO USE ESCAPELLE

Do not share medicines prescribed for you with any other person.

Always take ESCAPELLE exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

The tablet should be taken no later than 72 hours after unprotected intercourse.

ESCAPELLE tablet can be used on any day of the menstrual cycle.

If vomiting occurs within three to four hours of taking your tablet, another tablet should be taken immediately.

After using emergency contraception it is recommended to use a local barrier method (e.g. condom) until the next menstrual period starts. You can still continue to use your regular hormonal contraception.

ESCAPELLE is not recommended in children under the age of 16 years.

If you take more ESCAPELLE than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Overdose may cause nausea and vaginal bleeding.

4. POSSIBLE SIDE-EFFECTS

ESCAPELLE can have side-effects. Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects, please consult your doctor, pharmacist or other healthcare professional for advice.

You might experience the following side-effects:

Very common (more than 1 in 10): bleeding disturbances, nausea, fatigue, lower abdominal pain, and headache.

Common (more than 1 in 100): dizziness, breast tenderness, diarrhoea, and vomiting, irregular menstruation.

Although most women will have their next period at the usual time, some will have a later, or earlier than normal period. If your period is late by more than 5 days or you have it at the normal time but it is abnormal or if you suspect pregnancy (feeling sick, nausea, vomiting, breast tenderness etc), you should contact your doctor.

Side effects may include severe depression with a higher risk of suicidal thoughts/behavior and suicide.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ESCAPELLE.

5. How to store Escapelle

- Store at or below 25 ºC. Protect from light.
- Store the tablet in the original packaging until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN
- Do not use the tablets after the expiry date printed on the carton and blister.

- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Escapelle contains

The active substance is: levonorgestrel.

The inactive ingredients are colloidal anhydrous silica, lactose monohydrate, magnesium stearate, maize starch, potato starch and purified talc.

What Escapelle looks like and contents of the pack

Almost white, flat, rimmed tablet of about 8 mm diameter, with an impression mark of “G00” on one side.

The folded carton of ESCAPELLE contains one aluminium/PVC blister of one tablet.

Holder of Certificate of Registration

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