PATIENT INFORMATION LEAFLET FOR ESTELO

SCHEDULING STATUS

S2

ESTELO 1,50 mg tablets

Levonorgestrel

ESTELO contains sugar (lactose monohydrate, 43,30 mg)

Read all of this leaflet carefully because it contains important information for you

ESTELO is available without a doctor's prescription. Nevertheless, you still need to take ESTELO carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ESTELO with any other person.
- Ask your pharmacist if you need more information or advice.

What is in this leaflet

1. What ESTELO is and what it is used for

2. What you need to know before you take ESTELO

3. How to take ESTELO

4. Possible side effects

5. How to store ESTELO

6. Contents of the pack and other information

1. What ESTELO is and what it is used for

ESTELO is used as an emergency birth control method.

ESTELO can be used to help prevent a pregnancy when taken within 72 hours (3 days) after having unprotected sex, or if your usual method of birth control has failed (e.g., a broken condom).

ESTELO is intended for occasional use only. You should not use it on a regular basis, or as a substitute for long-term contraception.

2. What you need to know before you take ESTELO

Do not take ESTELO:

- If you are hypersensitive (allergic) to levonorgestrel or any of the other ingredients of ESTELO (see section 6).
- If you have severe liver problems.
- If you are pregnant or suspect that you are pregnant.
- If you suffer from bleeding between your regular menstrual cycles (periods) that has not been diagnosed by your doctor, or if you have a history of or current high risk of arterial disease.
- If you had already taken ESTELO within the same monthly cycle.
- If you have depression, which is not well controlled with treatment.
- If you had depression with previous use of hormonal contraceptives.

Warnings and precautions

Take special care with ESTELO:

- ESTELO is only intended for occasional use and should not be taken on a regular basis, or as a substitute for long-term birth control. Talk to your doctor or pharmacist about long-term birth control methods.
- If you still become pregnant after using ESTELO, your doctor will closely evaluate you for an ectopic pregnancy especially if you have a history of an ectopic pregnancy,

fallopian tube surgery or a pelvic inflammatory disease.

- A previous ectopic pregnancy and a previous infection of the fallopian tubes increase the risk of a new ectopic pregnancy.
- If you have a disease of your small bowel (such as Crohn's disease) that inhibits the absorption of ESTELO.
- The use of ESTELO does not protect you against sexually transmitted diseases (STDs). If you are worried about a sexual transmitted disease, talk to your doctor or pharmacist.

Tell your doctor before using ESTELO:

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

Hormonal contraceptives including ESTELO, may cause mood changes and depression, which may be severe. Severe depression is associated with a higher risk of suicidal thoughts/behaviour (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.

After you have taken ESTELO, you are advised to make an appointment to see your doctor about three weeks later, to make sure that ESTELO 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 ESTELO, it is important that you see your doctor.
Your doctor can also tell you about long-term methods of contraception which are more effective in preventing you from getting pregnant.

After you have taken ESTELO, if you want to have sex, and are not using the contraceptive pill, you should use additional contraception methods (e.g., condoms or a cap plus spermicide) until your next menstrual period.
This is because ESTELO 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 ESTELO (also if this is during the same menstrual cycle), ESTELO will not exert its contraceptive effect and there is again the risk of pregnancy.
There is some evidence that ESTELO may be less effective with increasing body weight or body mass index (BMI), but these data were limited and inconclusive.
Therefore, ESTELO is still recommended for all women regardless of their weight or BMI.

Children and adolescents

ESTELO is not recommended in children or adolescents under 16 years.

Other medicines and ESTELO

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are currently using:

- Medicines used for the treatment of the human immunodeficiency virus (HIV) (ritonavir, efavirenz).

- Medicines used to treat epilepsy (phenobarbitone, phenytoin, primidone and carbamazepine).
- Herbal remedies containing St. John's wort (*Hypericum perforatum*) (used to treat depression).
- Medicines used to treat tuberculosis (rifampicin, rifabutin).
- Medicine used to treat fungal infections (griseofulvin).
- Medicines used to treat bacterial infections (antibiotics, such as ampicillin).
- Medicines used to prevent organ rejection after a transplant (ciclosporin).

Some medicines may prevent ESTELO from working effectively.
If you have used any of the medicines above during the last 4 weeks, ESTELO 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).

ESTELO with food and drink

See section 3.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking ESTELO.

Pregnancy:

Do not take ESTELO if you are pregnant.

If you do become pregnant even after taking ESTELO, it is important that you see your doctor. There is no evidence that ESTELO will harm a baby that develops in your uterus/ womb if you use ESTELO 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 ESTELO or if you have previously had an ectopic pregnancy, fallopian tube surgery or pelvic inflammatory disease.

Breastfeeding:

The active ingredient of ESTELO is excreted into your breast milk. Therefore, it is suggested that you take your tablet immediately after a breastfeeding and avoid nursing at least 6 hours following ESTELO administration.

Fertility:

ESTELO increases the possibility of changes in your menstruation cycle which can sometimes lead to you having an earlier or later ovulation date resulting in a modified fertility date. Although there are no fertility data in the long term, after treatment with ESTELO a rapid return to fertility is expected and therefore, you should initiate or continue with regular contraception as soon as possible after ESTELO use.

Driving and using machines

ESTELO may cause side effects, such as dizziness and may impair your ability to drive a vehicle and use machines or perform other skilled tasks. Take special care before performing tasks requiring your attention, until you know how ESTELO affects you.

ESTELO contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ESTELO.

3. How to take ESTELO

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

Always take ESTELO exactly as your pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take ESTELO as soon as possible, preferably within 12 hours, and no later than 72 hours (3 days) after you had unprotected sex. Do not delay taking ESTELO.
ESTELO 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.

Take 1 tablet as soon as possible after unprotected sex.

You should swallow ESTELO whole with some liquid. It can be taken with or without food, according to your preference.
If you vomit within 3 to 4 hours after taking ESTELO you should take another dose immediately.

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 you have the impression that the effect of ESTELO is too strong or too weak, tell your doctor or pharmacist.

If you take more ESTELO than you should
Although there have been no reports of serious harmful effects from taking too much of ESTELO at once, you may feel sick or have vaginal bleeding.
In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
Take this leaflet with you so the doctor will know what you have taken.

4. Possible side effects

ESTELO can have side effects.

Not all side effects reported for ESTELO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ESTELO, please consult your health care provider for advice.

If any of the following happens, stop taking ESTELO and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ESTELO. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.
- Suicidal thoughts/behaviour and suicide.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headaches or dizziness.
- Nausea (feeling sick), vomiting (being sick) lower abdominal pain, diarrhoea.
- Changes in your menstrual cycle (period), irregular bleeding, vaginal bleeding not

related to your menstrual cycle.

- Breast tenderness.
- Fever, feeling tired.

Less frequent side effects:

- Breast enlargement in men.
- Changes in your libido (sex drive).
- Changes in your liver enzyme results when blood tests are done.
- Pain in your stomach area.
- Hives (red, raised, itchy skin rash).
- Painful menstruation with abdominal cramps, pelvic pain.
- Swelling of your face.

Side effects with unknown frequency:

- Changes in your appetite or body mass.
- Feeling depressed (depression), inability to sleep.
- Drowsiness.
- Stomach problems.
- Acne (pimples).
- Patchy, brown discolouration of your skin.
- Hair loss (temporary) or abnormal hair growth in women.
- Breast changes, premenstrual syndrome-like symptoms (mood swings, tender breasts, food cravings, tiredness, feeling irritable or depressed).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you experience side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

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 ESTELO.

5. How to store ESTELO

Store all medicines out of reach of children.

Store at or below 25 ºC.

Do not take after the expiry date stated on the package.

Return all unused medicine to your pharmacist.

Do not dispose of unused tablets in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What ESTELO contains

The tablet contains 1,50 mg levonorgestrel.

ESTELO contains sugar (lactose monohydrate, 43,30 mg).

The other ingredients are cellulose microcrystalline, croscarmellose sodium, lactose monohydrate, magnesium stearate, poloxamer 188.

What ESTELO looks like and contents of the pack

ESTELO is a round, biconvex, white tablet, engraved with "C" on one side and "1" on the other side.

Clear to slightly opaque PVC-PVDC/Aluminium foil blister strip packed in an outer carton.

Pack size: 1 tablet.

Holder of certificate of registration

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Registration number

52/21.8.2/1021