
PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

VONEL 0,75 mg tablets

Levonorgestrel

Contains sugar: 84,5 mg lactose monohydrate per tablet.

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

VONEL is available without a doctor's prescription, for you to use as an emergency contraception. Nevertheless, you still need to use VONEL carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share VONEL with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if you think you are pregnant after taking VONEL.

What is in this leaflet:

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

1. What VONEL is and what it is used for

VONEL contains the active ingredient levonorgestrel, which is a synthetic derivative of the naturally occurring female sex hormone. Levonorgestrel belongs to the group of emergency birth control methods commonly known as "the morning after pill". Levonorgestrel prevents ovulation (stopping your ovaries from releasing an egg) and fertilisation (preventing sperm from fertilising any egg you may have already released). It also may work by changing the lining of the uterus (womb) to prevent development of a pregnancy.

VONEL 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).

2. What you need to know before you take VONEL

Do not take VONEL:

- If you are hypersensitive (allergic) to levonorgestrel or any of the other ingredients of VONEL (listed in section 6).
- If you are pregnant or suspect that you are pregnant. Do not take VONEL if your last menstrual cycle (period) has not taken place as usual, or if you have already had unprotected sex, or failure of your regular birth control methods after your last menstrual cycle (period) (see section 2, "Pregnancy and breastfeeding").
- If you suffer from bleeding between your regular menstrual cycles (periods) that has not been diagnosed by your doctor.
- If you have a history of arterial disease (a common circulatory problem in which narrowed arteries reduce blood flow to your limbs).
- If you have severe liver problems.
- If you have depression, which is not well controlled with treatment.
- If you have had depression with previous use of hormonal contraceptives.

Warnings and precautions:

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 sooner you take it after having unprotected sex, or failure of your usual birth control method, the more effective it is.

VONEL is intended for occasional use only and should not be taken on a regular basis, or as a substitute for long-term birth control.

VONEL will not stop a pregnancy if you are already pregnant.

Do not use VONEL repeatedly within a menstrual cycle; it may disturb your cycle. After you have taken VONEL, 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.

Take special care with VONEL:

- If you are at risk of developing an ectopic pregnancy (a pregnancy in which the fetus develops outside the womb, typically in a fallopian tube) (e.g., you have had an ectopic pregnancy before or you have had an infection of your fallopian tubes).
- If you still become pregnant after using emergency contraception. Your doctor will closely evaluate you for an ectopic pregnancy.
- If you have breast cancer.
- If you have blood in your urine and you have not been to your doctor.
- If you have a serious liver problem, the use of VONEL is not recommended (see section 2, “Do not take VONEL”).
- If you suffer from Crohn’s disease, this disease may impair the efficacy of VONEL.
- If you suffer from depression, the use of VONEL is not recommended (see section 2, “Do not take VONEL”).
- Hormonal contraceptives, including VONEL, 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.
- If you have high blood pressure.
- If you have heart or kidney problems.
- If you suffer from asthma.
- If you suffer from seizures.
- If you have migraines.
- If you have diabetes (high blood sugar).
- If you suffer from porphyria (a genetic disorder characterised by a disturbance in porphyrin metabolism with resultant increase in the formation and excretion of porphyrins).
- The use of VONEL does not replace regular contraception or protect against sexually transmitted diseases (STDs).
- You should consult your doctor within 3 weeks after you have taken VONEL, whether or not bleeding has occurred.

Children and adolescents

VONEL is not recommended for young women under 16 years of age. If you are under 16, you must visit your doctor or family planning clinic to get emergency contraception.

Other medicines and VONEL:

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

The following medicines may cause an interaction when used in combination with VONEL:

- Phenobarbitone, phenytoin, primidone or carbamazepine (used to treat seizures (convulsions or fits)).
- Ampicillin and other antibiotics, including medicines used to treat tuberculosis such as rifabutin or rifampicin.
- Griseofulvin (used to treat fungal infection on your skin).
- Ritonavir and Efavirenz (used to treat HIV infection).
- Herbal medicines containing St John's wort (used for depression).
- Ciclosporin (used to reduce the activity of your immune system and to prevent organ rejection after transplants).

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

VONEL with food, drink and alcohol:

VONEL can be taken with or without food.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think that 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 VONEL.

Do not take VONEL if you are pregnant or suspect that you are pregnant. Contact your doctor

immediately if you suspect you are pregnant.

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

Very small amounts 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 breastfeeding session and avoid nursing for 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.

VONEL increases the possibility of menstruation disturbance which can sometimes lead to an earlier or later ovulation date resulting in modified fertility date. Although there are no fertility data in the long term, after treatment with VONEL a rapid return to fertility is expected and therefore, regular contraception should be continued or initiated as soon as possible after VONEL use.

Driving and using machines:

VONEL may impair your ability to drive and use machinery. Do not drive, operate machinery, or do anything else that require your attention until you know how VONEL affects you.

VONEL contains lactose monohydrate:

If you have been told by your doctor that you have an intolerance to some sugars (that you cannot digest some sugars), contact your doctor before taking VONEL.

3. How to take VONEL

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

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

VONEL can be taken on any day of the menstrual cycle.

The usual dose is 2 tablets, taken as one single dose, as soon as possible. You should take VONEL preferably within 12 hours and not later than 72 hours (3 days) after having unprotected sex, or failure of your regular birth control method.

VONEL can be taken with or without food.

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

After using emergency contraception, it is recommended that you should not have any unprotected sex until your next menstrual cycle (period) has taken place. Until then you must use mechanical or chemical birth control methods (e.g., condoms, foams or pessaries). You can still continue to use your regular hormonal contraception.

VONEL cannot prevent pregnancy once a fertilised ovum has been implanted in your uterus.

If you take more VONEL than you should:

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Overdose may cause nausea and vaginal bleeding.

There are no specific antidotes for VONEL overdose and treatment provided will be symptomatic and supportive.

If you forget to take VONEL:

You must not take VONEL more than 72 hours (3 days) after you have had unprotected sex, or failure of your birth control methods.

4. Possible side effects

VONEL can have side effects.

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

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

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

These are all very serious side effects. If you have them, you may have had a serious reaction to VONEL. 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 your skin and eyes, also called jaundice.
- Fever.
- Formation of blood clots in your body (pain, tenderness, redness or swelling in the area of the clot).
- Cushing's syndrome (hormonal disorder caused by high levels of the hormone cortisol in your body) or extreme fatigue, lack of appetite, severe abdominal pain, nausea, vomiting or low blood pressure. This may indicate that you have adrenal insufficiency (low cortisol levels).

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:

- Changes in your menstrual cycle (period) or irregular bleeding.
- Drowsiness.
- Feeling nervous, depressed or changes in your mood.
- Headache or dizziness.
- Nausea (feeling sick), vomiting (being sick), diarrhoea, stomach pain or cramping.
- Changes in your breasts (enlargement, tenderness, pain or milk production).
- Tiredness or weakness.
- Swelling due to fluid retention.
- Enlargement of your ovaries or cyst formation on your ovaries.

Less frequent side effects:

- Difficulty sleeping or sleeplessness.
- Low blood pressure (dizziness or light-headedness).
- Patchy, brown discolouration of your skin.
- Hot flushes.
- Hair loss (temporary) or abnormal hair growth.
- Acne (pimples).

Frequency unknown:

- Changes in your appetite or weight.
- Weakening of your bone structure or osteoporosis (easy bone fractures).
- Mental depression.

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

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of VONEL.

Suspected adverse reactions can also be reported directly to the HCR via email: pharmacovigilance.africasme@sunpharma.com or tel: +27(0) 12 643 2000.

5. How to store VONEL

Store at or below 25 °C. Protect from light.

Keep blister strip in outer carton until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use after the expiry date printed on the label or carton.

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 VONEL contains:**

The active substance is levonorgestrel.

Each tablet contains 0,75 mg levonorgestrel as active ingredient.

The other ingredients are colloidal silicon dioxide, corn starch, hypromellose, lactose monohydrate, magnesium stearate and talcum.

What VONEL looks like and contents of the pack:

White to off-white, circular, flat faced, bevelled edge, uncoated tablet, debossed with “403” on one side and plain on the other side.

Content of the packaging:

Silver aluminium/clear PVC blister strip containing 2 tablets. One blister strip is packed into an outer carton.

Pack size: 2 tablets.

Holder of certificate of registration and manufacturer:

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road

Stormill, Ext. 1

Roodepoort

Johannesburg 1724

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This leaflet was last revised:

26 January 2026

Registration number:

49/21.8.2/0574

Date of registration:

30 September 2016

Namibia NS1 20/18.7/0105

Access to the corresponding PIL translation:

The PIL is available in one other language (Afrikaans), a copy is accessible on the company website: <https://sunpharma.com/south-africa-products/>