Patient Information Leaflet for VONEL

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 still 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 (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:

See section 3.

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.

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 6 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.

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.

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 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.

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

Once you have used VONEL, 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).

If you have the impression that the effect of VONEL is too strong or too weak, talk to your doctor or pharmacist.

If you take more VONEL than you should:

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

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 "**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 VONEL.

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

Tel. no.: 011 495 0100

Signed:

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Signed:

Patient Information Leaflet for VONEL

PASIËNTINLIGTINGBLAD

SKEDULERINGSTATUS: S2

VONEL 0,75 mg tablette

Levonorgestrel

Bevat suiker: 84,5 mg laktosemonohidraat per tablet.

Lees hierdie hele inligtingblad noukeurig deur aangesien dit belangrike inligting vir jou bevat:

VONEL is vir jou beskikbaar sonder ‘n dokter se voorskrif om as nood-voorbehoeding te gebruik. Jy moet VONEL nogtans steeds met sorg gebruik om die beste resultate daarvan te kry.

- Hou hierdie inligtingsblad. Dit mag vir jou nodig wees om dit weer te lees.
- Moenie VONEL met enige ander persoon deel nie.
- Vra jou gesondheidsorgverskaffer of apteker as jy meer inligting of advies benodig.
- Jy moet jou dokter gaan sien as jy dink dat jy steeds swanger is nadat jy VONEL geneem het.

Wat is in hierdie inligtingsblad:

1. Wat is VONEL en waarvoor word dit gebruik

2. Wat jy moet weet voordat jy VONEL neem

Signed: JMR

3. Hoe om VONEL te neem

4. Moontlike newe-effekte

5. Hoe om VONEL te bewaar

6. Inhoud van die pakkie en ander inligting.

1. Wat is VONELen waarvoor word dit gebruik

VONEL bevat die aktiewe bestanddeel, levonorgestrel, wat ‘n sintetiese derivaat is van die vroulike geslagshormoon wat natuurlik voorkom. Levonorgestrel behoort aan ‘n groep van nood-geboortebeperkingsmetodes wat algemeen bekend staan as “the morning after pill”. Levonorgestrel voorkom ovulasie (verhoed dat jou eierstokke die eiersel vrystel) en bevrugting (voorkom dat die sperm enige eiersel bevrug wat dalk alreeds vrygestel is). Dit kan ook werk deur die voering van die uterus (baarmoeder) te verander om ontwikkeling van swangerskap te voorkom.

VONEL kan gebruik word om swangerskap te help voorkom wanneer dit binne 72 uur (3 dae) ná onbeskermde geslagsomgang, of as jou normale metode van geboorteperking gefaal het (bv. ‘n kondoom wat gebreek het) geneem word.

2. Wat jy moet weet voordat jy VONEL neem

Moenie VONEL neem nie:

- As jy hipersensitief (allergies) is vir levonorgestrel of vir enige van die ander bestanddele van VONEL (gelys in afdeling 6).
- As jy swanger is of vermoed dat jy swanger mag wees. Jy moenie VONEL neem as jou vorige menstruasie-siklus (maandstonde) nie soos gewoonlik plaasgevind het nie, of as jy alreeds onbeskermde geslagsomgang gehad het of as jou normale geboortebeperkingsmetodes na jou

vorige menstruasie-siklus (maandstonde) misluk het (sien afedeling 2, “Swangerskap en borsvoeding”).

- As jy aan bloeding tussen gereelde menstrusiesiklusse (maandstondes) ly wat nie deur jou dokter gediagnoseer is nie.
- As jy ‘n geskiedenis van arteriële siekte het (‘n algemene sirkulasieprobleem waar vernoude arteries bloedvloei na jou ledemate inperk).
- As jy ernstige lewerprobleme het.
- As jy depressie het, wat nie goed gekontroleer is met behandeling nie.
- As jy voorheen depressie gehad het met die gebruik van hormonale voorbehoedmiddels

Waarskuwings en voorsorgmaatreëls:

Jy kan alreeds swanger wees as:

- jou maandstonde meer as 5 dae laat is, of as jy ongewone bloeding ondervind wanneer jou volgende maandstonde behoort plaas te vind;
- jy meer as 72 uur gelede, of sedert jou vorige maandstonde, onbeskermde geslagsomgang gehad het.

Hoe gouer jy die tablette neem nadat jy onbeskermde geslagsomgang gehad het of na mislukking van jou normale geboortebeperkingsmetode, hoe meer doeltreffend is die tablette.

VONEL is slegs bedoel om af en toe gebruik te word en moenie op ‘n gereelde basis gebruik word nie of as ‘n plaasvervanger vir langtermyn-geboortebeperking nie.

VONEL sal nie ‘n swangerskap stuit as jy alreeds swanger is nie.

Moenie VONEL herhaaldelik binne ‘n menstruasiesiklus gebruik nie; dit kan jou siklus omvergooi.

Nadat jy VONEL geneem het, is dit belangrik dat jy ‘n afspraak met jou dokter moet maak om hom te raadpleeg oor gereelde metodes van voorbehoeding wat vir jou geskik is.

Signed: JMR

Tref spesiale voorsorg met VONEL:

- As daar ‘n risiko bestaan dat jy ‘n ektopiese swangerskap sal ontwikkel (‘n swangerskap waarin die fetus buite die baarmoeder ontwikkel, tipies in ‘n Fallopius-buis) (bv. as jy al voorheen ‘n ektopiese swangerskap gehad het of as jy ‘n infeksie in jou Fallopius-buise gehad het).
- As jy steeds swanger geraak het nadat jy nood-voorbehoeding gebruik het. Jou dokter sal jou deeglik evalueer vir ‘n ektopiese swangerskap.
- As jy borskanker het.
- As jy bloed in jou urine het en jy nie by jou dokter was nie.
- As jy ‘n ernstige lewerprobleem het, word die gebruik van VONEL nie aanbeveel nie (sien afdeling 2, “Moenie VONEL neem nie”).
- As jy aan Crohn se siekte ly, hierdie siekte kan die doeltreffendheid van VONEL belemmer.
- As jy aan depressie ly, word die gebruik van VONEL nie aanbeveel nie (sien afdeling 2, “Moenie VONEL neem nie”).
- Hormonale voorbehoedmiddels, insluitend VONEL, kan gemoedsveranderinge en depressie veroorsaak wat ernstig kan wees. Ernstige depressie word geassosieer met ‘n hoër risiko van selfdoodgedagtes/gedrag (bv. praat van selfdood, onttrekking van sosiale kontak, veranderinge in gemoedstoestande, behep is met die dood of geweld, hopeloos voel oor ‘n situasie, toenemende gebruik van alkohol/substanse, om selfvernietigende dinge te doen, persoonlikheidsveranderinge) en selfdood. As jy gemoedsveranderinge en depressie ervaar, moet jy jou dokter raadpleeg vir advies.
- As jy hoë bloeddruk het.
- As jy hart- of nierprobleme het.
- As jy aan asma ly.
- As jy aan toevalle ly.
- As jy migraine kry.
- As jy diabetes het (hoë bloedsuiker).

- As jy aan porfirie ly (‘n genetiese versteuring gekenmerk deur ‘n versteuring in porfirienmetabolisme met die gevolglike verhoging in die vorming en uitskeiding van porfiriene).
- Die gebruik van VONEL vervang nie normale voorbehoeding nie of beskerm nie teen seksueeloordraagbare siektes nie.
- Jy moet jou dokter binne 3 weke raadpleeg nadat jy VONEL geneem het, ongeag of bloeding voorgekom het.

Kinders en adolessente

VONEL word nie aanbeveel by vroue jonger as die ouderdom van16 jaar nie. As jy onder die ouderdom van 16 jaar is, moet jy jou dokter of gesinsbeplanningskliniek besoek om noodvoorbehoeding te verkry.

Ander medisyne en VONEL:

Lig jou gesondheidsorgverskaffer altyd in as jy enige ander medisyne gebruik. (Dit sluit komplementêre of tradisionele medisyne in.)

Die volgende medisyne kan ‘n wisselwerking veroorsaak wanneer dit saam met VONEL gebruik word:

- fenobarbitoon, fenitoïen, primidoon of karbamasepien (gebruik om toevalle (konvulsies of aanvalle) te behandel.
- Ampisillien en ander antibiotika, insluitende medisyne wat gebruik word om tuberkulose te behandel soos rifabutien of rifampisien.
- Griseofulvien (gebruik om swaminfeksie op jou vel te behandel).
- Ritonavir (gebruik om MIV-infeksie te behandel).

- Kruiemiddels wat Johanneskruid bevat (gebruik om depressie te behandel).
- Siklosporien (gebruik om die aktiwiteit van jou immuunstelsel te onderdruk en om verwerping ná orgaanoorplanting te voorkom).

Sommige medisyne kan die doeltreffendheid van VONEL voorkom. Indien jy enige van bogenoemde medisyne gedurende die afgelope 4 weke gebruik het, kan VONEL minder geskik vir jou wees. Jou dokter kan ‘n ander soort (nie-hormonale) noodvoorbehoeding, d.i. ‘n koper-intrauterine toestel (Cu-IUD) voorskryf. As dit nie ‘n opsie vir jou is nie of as jy nie jou dokter dadelik kan gaan sien nie, kan jy ‘n dubbele dosis VONEL neem.

VONEL saam met voedsel, drinkgoed en alkohol:

Sien afdeling 3.

Swangerskap en borsvoeding:

As jy swanger is of borsvoed, vermoed dat jy swanger mag wees of as jy beplan om swanger te raak, moet jy asseblief jou dokter, apteker of ander gesondheidsorgverskaffer raadpleeg vir advies voordat jy VONEL neem.

Moenie VONEL neem as jy swanger is of vermoed dat jy swanger mag wees nie. Kontak jou dokter dadelik as jy vermoed dat jy swanger is.

Baie klein hoeveelhede van die aktiewe bestanddeel van hierdie medisyne kan in die borsmelk voorkom. Daar word nie gereken dat dit nadelig vir jou baba mag wees nie, maar as jy bekommerd is, kan jy jou tablet onmiddellik ná ‘n borsvoedingsessie neem en verhoed om vir ten minste 6 uur nadat die tablet geneem is, te borsvoed. Op hierdie manier, deur jou tablet betyds voor die volgende

voeding te neem, verminder jy die hoeveelheid aktiewe bestanddeel wat jou baba saam met die borsmelk sal inneem.

Bestuur en gebruik van masjinerie:

VONEL kan jou vermoë om motor te bestuur of masjinerie te hanteer belemmer. Moenie motor bestuur, masjinerie hanteer of enigiets anders wat jou aandag vereis doen nie totdat jy weet hoe VONEL jou affekteer.

VONEL bevat laktosemonohidraat:

As jou dokter jou gesê het dat jy ‘n onverdraagsaamheid teenoor sekere suikers het (dat jy sekere suikers nie kan verteer nie), moet jy jou dokter kontak voordat jy VONEL neem.

3. Hoe om VONEL te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem VONEL altyd presies soos aangedui in hierdie inligtingsblad of soos wat jou dokter, apteker of verpleegkundige jou aangesê het om dit te gebruik. Kontroleer met jou dokter, apteker of verpleegkundige as jy onseker is.

Die normale dosis is 2 tablette, geneem as ‘n enkeldosis, so gou as moontlik. Jy moet VONEL verkieslik binne 12 uur neem en nie later as 72 uur (3 dae) nadat jy onbeskermde geslagsomgang gehad het of mislukking van jou normale geboortebeperkingsmetode nie.

VONEL kan met of sonder voedsel geneem word.

As braking binne drie tot vier uur nadat jy die tablette geneem het voorkom, moet jy onmiddellik nog tablette neem.

Nadat noodvoorbehoeding geneem is, word dit aanbeveel dat ‘n plaaslike skansmetode gebruik word (bv. kondoom) totdat die volgende menstruasieperiode begin. Jy kan steeds voortgaan om normale hormonale voorbehoeding te gebruik.

VONEL kan nie swangerskap voorkom wanneer ‘n bevrugte eiersel reeds in jou uterus ingeplant is nie.

Sodra jy VONEL gebruik het, moet jy nie enige onbeskermde geslagsomgang hê totdat jou volgende menstruasiesiklus (maandstonde) plaasgevind het nie. Tot dan moet jy meganiese of chemiese voorbehoedingsmetodes (bv. kondome, skuim of vaginale setpille) gebruik.

Praat met jou dokter of apteker as jy onder die indruk is dat die uitwerking van VONEL te sterk of te swak is.

As jy meer VONEL geneem het as wat jy behoort te neem:

Konsulteer jou dokter of apteker in die geval van oordosering. Indien nie een van hulle beskikbaar is nie, gaan na die naaste hospitaal of gifbeheersentrum.
Oordosering kan naarheid en vaginale bloeding veroorsaak.

As jy vergeet het om VONEL te neem:

Jy moenie VONEL neem as daar alreeds 72 uur (3 dae) verloop het sedert jy onbeskermde geslagsomgang gehad het nie of as jou geboortebeperkingsmetodes misluk het nie.

4. Moontlike newe-effekte

VONEL kan newe-effekte hê.

Nie alle newe-effekte wat vir VONEL aangemeld word, is in hierdie inligtingsblad opgeneem nie. Indien jou algemene gesondheid versleg of as jy enige ongewenste effekte ervaar terwyl jy VONEL neem, moet jy asseblief jou gesondheidsorgverskaffer raadpleeg vir advies.

Indien enige van die volgende gebeur, hou op om VONEL te gebruik en lig jou dokter dadelik in of gaan na die noodgevalle-afdeling by jou naaste hospitaal:

- Swelling van jou hande, voete, enkels, gesig, lippe en mond of keel wat probleme met sluk of asemhaling kan veroorsaak.
- Uitslag en gejeuk.
- Floute.

Hierdie is almal baie ernstige newe-effekte. Indien jy dit ervaar, kon jy moontlik ‘n ernstige allergiese reaksie op VONEL gehad het. Jy mag dringende mediese bystand of hospitalisasie benodig.

Lig jou dokter dadelik in of gaan na die noodgevalle-afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

- Vergeling van jou vel en oë, ook geelsug genoem.
- Koors.
- Vorming van bloedklonte in jou liggaam (pyn, teerheid, rooiheid of swelling in die area van die klont).
- Cushing se sindroom (hormonale versteuring veroorsaak deur hoë vlakke van die hormoon, kortisol, in jou liggaam) of uitermatige moegheid, verlies aan aptyt, erge buikpyn, naarheid,

braking en lae bloeddruk. Dit kan ‘n aanduiding wees van adrenale ontoereikendheid (lae kortisolvlakke).

Hierdie is almal ernstige newe-effekte. Jy mag dringende mediese bystand benodig.

Lig jou dokter in as jy enige van die volgende opmerk:

Algemene newe-effekte:

- Veranderinge in jou menstruasiesiklus (maandstonde) of onreëlmatige bloeding.
- Lomerigheid.
- Voel senuweeagtig, bedruk of veranderinge in jou gemoedstoestand.
- Hoofpyn of duiseligheid.
- Naarheid (voel mislik), braking (gooi op), diarree, maagpyn of krampe.
- Veranderinge in jou borste (vergroting, teerheid, pyn of melkproduksie).
- Moegheid of swakheid.
- Swelling as gevolg van vogretensie.
- Vergroting van jou eierstokke of vorming van siste op jou eierstokke.

*Minder algemene newe-effekte***:**

- Sukkel om te slaap of slapeloosheid.
- Lae bloeddruk (duiseligheid of lighoofdigheid).
- Vlekkerigheid, bruin verkleuring van jou vel.
- Warm gloede.
- Haarverlies (tydelik) of abnormale haargroei.
- Aknee (puisies).

Voorkoms onbekend:

- Verandering in jou eetlus of gewig.
- Verswakking van jou beenstruktuur of osteoporose (maklike beenbreuke).
- Geestesbedruktheid.

Indien jy enige newe-effekte ondervind wat nie in hierdie inligtingsblad genoem word nie, lig asseblief jou dokter of apteker in.

Aanmelding van newe-effekte:

Praat met jou dokter of apteker as jy newe-effekte ondervind. Jy kan ook newe-effekte by SAHPRA *via* die "**Adverse Drug Reaction Reporting Form**" aanmeld, wat aanlyn beskikbaar is onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van VONEL te verskaf.

5. Hoe om VONEL te bewaar

Bewaar by of onder 25 °C. Beskerm teen lig.

Hou die stulpstrook in die buitenste karton tot benodig vir gebruik.

BEWAAR ALLE MEDISYNE BUITE DIE BEREIK VAN KINDERS.

Moenie ná die vervaldatum, soos op die etiket of karton gedruk, gebruik nie.

Bring alle ongebruikte medisyne terug na jou apteker.

Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pakkie en ander inligting

Wat VONEL bevat:

Die aktiewe bestanddeel is levonorgestrel.

Elke tablet bevat 0,75 mg levonorgestrel as aktiewe bestanddeel.

Die ander bestanddele is: kolloïdale silikondioksied, mieliestysel, hipromellose, laktosemonhidraat, magnesiumstearaat en talk.

Hoe VONEL lyk en inhoud van die verpakking:

Wit tot naaswit, plat, ronde, onbedekte tablet met afgeskuinste rante, ingepers met “403” op een kant en skoon op die ander kant.

Inhoud van die verpakking:

Silwer aluminium/helder PVC-slulpstrook wat 2 tablette bevat. Een stulpstrook word in ‘n buitenste karton verpak.

Pakgrootte: 2 tablette.

Houer van die registrasiesertifikaat en vervaardiger:

Ranbaxy Pharmaceuticals (Pty) Ltd

Lautreweg 14

Stormill, Uitbreiding 1

Roodepoort

Johannesburg 1724

Tel. nr.: 011 495 0100

Signed:

Hierdie inligtingstuk was laas hersien op:

03 Mei 2023

Registrasienommer:

49/21.8.2/0574

Datum van registrasie:

30 September 2016

Namibië NS1 20/18.7/0105

Signed: