PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

LEVONORGESTREL 1,5 UNICORN tablet

Levonorgestrel

Contains sugar: lactose monohydrate 43,3 mg per tablet.

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

LEVONORGESTREL 1,5 UNICORN is available without a doctor's prescription, for you to treat a condition. Nevertheless, you still need to use LEVONORGESTREL 1,5 UNICORN carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share LEVONORGESTREL 1,5 UNICORN with any other person.
- Ask your pharmacist if you need more information or advice.

What is in this leaflet:

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

1. What LEVONORGESTREL 1,5 UNICORN is and what it is used for

LEVONORGESTREL 1,5 UNICORN is an emergency oral contraceptive, which is used to prevent pregnancy. **LEVONORGESTREL 1,5 UNICORN** must be used within 72 hours (3 days) of having unprotected sexual intercourse or if your usual

contraceptive method has failed.

LEVONORGESTREL 1,5 UNICORN should only be used as an emergency contraceptive and is not suitable for regular contraception. It is not as reliable as regular oral hormonal contraceptives.

LEVONORGESTREL 1,5 UNICORN may not prevent a pregnancy every time and is more effective the sooner it is used.

LEVONORGESTREL 1,5 UNICORN does not work if you are already pregnant. **LEVONORGESTREL 1,5 UNICORN** can only prevent pregnancy if you take it within 72 hours of unprotected sex. It will not prevent you from becoming pregnant if you have unprotected sex after taking **LEVONORGESTREL 1,5 UNICORN**.

2. What you need to know before you take LEVONORGESTREL 1,5 UNICORN:

Do not take LEVONORGESTREL 1,5 UNICORN:

- If you are hypersensitive (allergic) to levonorgestrel or any of the other ingredients of LEVONORGESTREL 1,5 UNICORN (see “WHAT LEVONORGESTREL 1,5 UNICORN CONTAINS”).
- If you have severe liver problems.
- If you are or think you may be pregnant. This may be possible if you had unprotected sexual intercourse in the same cycle or if the last menstrual period has not occurred. LEVONORGESTREL 1,5 UNICORN will not work if you are already pregnant.
- You have depression, which is not well controlled with treatment.
- You have had depression with previous use of hormonal contraceptives.

Warnings and precautions

Tell your doctor before taking **LEVONORGESTREL 1,5 UNICORN**:

Take special care with **LEVONORGESTREL 1,5 UNICORN**:

You may already be pregnant if:

- You had unprotected sex more than 72 hours ago, and since your last period.
- Your menstrual period is more than 5 days late.
- You have experienced abnormal bleeding when your next period is due.

The use of **LEVONORGESTREL 1,5 UNICORN** *is not advised:*

- If you have ever had an ectopic pregnancy (when your baby develops outside the uterus/womb).
- If you have ever had a disease called salpingitis (inflammation of the fallopian tubes).
- If you have a disease of your small bowel that interferes with the way you digest or absorb your food (for example, Crohn's disease).
- If you are worried about sexually transmitted diseases. **LEVONORGESTREL 1,5 UNICORN**, or any other hormonal contraceptives, will not protect you against sexually transmitted diseases. Only condoms can do this. Consult your healthcare professional for advice if you are worried about this.
- If you are overweight or have a high body mass index (BMI). **LEVONORGESTREL 1,5 UNICORN** may be less effective with increasing body weight or BMI. This information is limited and inadequate, therefore, **LEVONORGESTREL 1,5 UNICORN** is still recommended for all women irrespective of their weight or BMI. It is recommended that all women should take emergency contraception as soon as possible after unprotected intercourse.
- Hormonal contraceptives including **LEVONORGESTREL 1,5 UNICORN**, 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 or depression, contact your healthcare provider for advice.

Children and adolescents

- If you are younger than 16 years old. **LEVONORGESTREL 1,5 UNICORN** should not be used unless your healthcare professional has advised you to.

Other medicines with LEVONORGESTREL 1,5 UNICORN:

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

- Medicines used in the treatment for HIV infection (such as efavirenz and ritonavir).
- Medicines used to treat epilepsy (such as carbamazepine, phenytoin and primidone).
- Herbal remedies containing St John's wort (*Hypericum perforatum*).
- Medicines used to treat tuberculosis (such as rifampicin and rifabutin).
- Griseofulvin, a medicine used to treat fungal infections.
- Antibiotics such as ampicillin.
- Cyclosporin, a medicine that suppresses the immune system.

Taking LEVONORGESTREL 1,5 UNICORN with food, drink and alcohol:

LEVONORGESTREL 1,5 UNICORN can be taken with or without food.

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 this medicine.

<u>Pregnancy</u>

Do not take **LEVONORGESTREL 1,5 UNICORN** if you are pregnant.

LEVONORGESTREL 1,5 UNICORN cannot interrupt a pregnancy.

LEVONORGESTREL 1,5 UNICORN will not work if you had unprotected sex more than 72 hours ago, and since your last menstrual period.

If you do become pregnant after taking **LEVONORGESTREL 1,5 UNICORN**, it is important that you consult your doctor. There is no information that suggests that **LEVONORGESTREL 1,5 UNICORN** will harm your baby, but your doctor should confirm that the pregnancy is not ectopic (when your baby develops outside your uterus/womb). It is important to inform your doctor if you develop severe abdominal pain after taking **LEVONORGESTREL 1,5 UNICORN** or if you already had an ectopic pregnancy, fallopian tube surgery or pelvic inflammatory disease.

Breastfeeding

Very small amounts of levonorgestrel may be secreted in your breast milk. To prevent adverse effects in your baby, you should take **LEVONORGESTREL 1,5 UNICORN** immediately after you breastfeed and avoid feeding directly after you take **LEVONORGESTREL 1,5 UNICORN**.

Driving and using machines

There is no information available on the use of **LEVONORGESTREL 1,5 UNICORN** affecting your ability to drive or operate machinery. However, therefore, you should not drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether **LEVONORGESTREL 1,5 UNICORN** affects your ability to perform such activities.

Important information about some of the ingredients of LEVONORGESTREL 1,5 UNICORN:

LEVONORGESTREL 1,5 UNICORN contains a sugar called lactose monohydrate.

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

your doctor before taking LEVONORGESTREL 1,5 UNICORN.

3. How to take LEVONORGESTREL 1,5 UNICORN:

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

Always take LEVONORGESTREL 1,5 UNICORN exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure.

Take 1 (one) tablet of **LEVONORGESTREL 1,5 UNICORN** as soon as possible. This should be within 12 hours, and no later than 72 hours (3 days) after you had unprotected sexual intercourse.

If you vomit after taking **LEVONORGESTREL 1,5 UNICORN**:

If you experience vomiting within three hours of taking **LEVONORGESTREL 1,5 UNICORN**, you will need to take another tablet. Contact your healthcare professional immediately for another tablet of **LEVONORGESTREL 1,5 UNICORN**.

You can take **LEVONORGESTREL 1,5 UNICORN** at any time in your menstrual cycle, unless your menstrual period is already late, you are already pregnant or think you may be pregnant.

You should avoid unprotected sexual intercourse until your next menstrual period. During this time, you should make use of mechanical and/or chemical methods of contraception (such as condoms, diaphragm, or a cervical cap). If you are already using a regular method of contraception, such as the contraceptive pill, you can continue to take it at your regular tablet-taking times.

Do not delay taking the tablet. **LEVONORGESTREL 1,5 UNICORN** works better the earlier you take it after having unprotected sex. Even at high doses, **LEVONORGESTREL 1,5 UNICORN** cannot prevent a pregnancy once the fertilised egg has become implanted in the uterus.

How often can you use **LEVONORGESTREL 1,5 UNICORN**:

LEVONORGESTREL 1,5 UNICORN should only be used in emergencies and not as a regular method of contraception. If you use **LEVONORGESTREL 1,5 UNICORN** more than once in a menstrual cycle it may disturb your menstrual cycle (menstrual period).

LEVONORGESTREL 1,5 UNICORN is not as effective as regular methods of contraception. Your healthcare professional will inform you about long-term methods of contraception, which will be more effective in preventing pregnancy.

If unprotected sexual intercourse occurs again after using **LEVONORGESTREL 1,5 UNICORN** (especially in the same menstrual cycle), **LEVONORGESTREL 1,5 UNICORN** will not be effective and you may be at risk of pregnancy again.

After the use of **LEVONORGESTREL 1,5 UNICORN**, your period may be different. If your menstrual period is late, abnormally light or abnormally heavy, consult your doctor as soon as possible to check whether you are pregnant.

If you take more LEVONORGESTREL 1,5 UNICORN 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.

If you take too many tablets of **LEVONORGESTREL 1,5 UNICORN**, you may experience nausea or withdrawal vaginal bleeding. You should ask your healthcare professional for advice, especially if you have been sick, as **LEVONORGESTREL 1,5 UNICORN** may not have worked correctly.

If you forget to take LEVONORGESTREL 1,5 UNICORN:

It is important that you do not miss any doses. If you miss a dose of **LEVONORGESTREL 1,5 UNICORN**, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule once daily.

Do not take a double dose to make up for the forgotten individual doses.

LEVONORGESTREL 1,5 UNICORN is supplied as a single tablet for once off use.

If you stop taking LEVONORGESTREL 1,5 UNICORN

Do not stop taking LEVONORGESTREL 1,5 UNICORN unless your doctor tells you to do so. If you have further questions on the use of LEVONORGESTREL 1,5 UNICORN, ask your doctor or pharmacist

LEVONORGESTREL 1,5 UNICORN is supplied as a single tablet for once off use. If you experience vomiting, please read the section "**If you vomit after taking LEVONORGESTREL 1,5 UNICORN**".

4. Possible side effects

LEVONORGESTREL 1,5 UNICORN can have side effects.

Not all side effects reported for **LEVONORGESTREL 1,5 UNICORN** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving **LEVONORGESTREL 1,5 UNICORN**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **LEVONORGESTREL 1,5 UNICORN** 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 or itching
- Fainting
- Yellowing of the skin and eyes, also called jaundice.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **LEVONORGESTREL 1,5 UNICORN**. 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:

- Chest pain
- Angina
- Changes in the way your heart beats e.g. if you notice it beating faster
- Difficulty in breathing
- Less urine than is normal for you.

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

Tell your doctor if you notice any of the following:

The following side effects have frequently been reported:

- Headaches and dizziness
- Diarrhoea, lower abdominal pain, nausea or being sick (vomiting). If you experience vomiting, please read the section "**If you vomit after taking LEVONORGESTREL 1,5 UNICORN**"
- Irregular bleeding or spotting before your next menstrual period
- Breast tenderness
- Your period may be different. It may be earlier or later than the expected date. If your period is more than 5 days late, is unusually light or unusually heavy, contact your healthcare professional as soon as possible
- Feeling tired.

The following side effects have been reported less frequently:

- Abdominal pain
- Itching, rash or hives (raised, itchy areas of skin)
- Painful menstruation or pain in the pelvic area
- Swelling of the face.

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

If you get side effects, talk to your doctor 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.

Side effects can also be reported directly to Unicorn Pharmaceuticals (Pty) Ltd at vigiiance@unicornpharma.co.za.

By reporting side effects, you can help provide more information on the safety of **LEVONORGESTREL 1,5 UNICORN**.

5. How to store LEVONORGESTREL 1,5 UNICORN:

Store at or below 25 ºC.

Store in the original packaging.

Do not take **LEVONORGESTREL 1,5 UNICORN** after the expiry date stated on the carton.

Return all unused **LEVONORGESTREL 1,5 UNICORN** to your pharmacist.

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

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What LEVONORGESTREL 1,5 UNICORN contains

The active ingredient is levonorgestrel.

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

What LEVONORGESTREL 1,5 UNICORN looks like and contents of the pack

Tablet.

Round, biconvex, with a diameter of 6,0 mm approximately and white in colour. The tablet is engraved with 'C' on one side and '1' on the other.

A pack size of 1 tablet packed in a blister pack consisting of aluminium push-through foil and clear, transparent PVC/PVDC film, in an outer unit carton box with a leaflet.

Holder of Certificate of Registration

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This leaflet was last revised in

October 2023

Registration number

53/21.8.2/0608