

WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.**

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

* https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[RH031 trade name][†]

Levonorgestrel

If you are a carer or parent looking after the person who takes this medicine, use this leaflet to give the medicine correctly and take note of the warnings and side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [RH031 trade name] is and what it is used for
2. What you need to know before you take [RH031 trade name]
3. How to take [RH031 trade name]
4. Possible side effects
5. How to store [RH031 trade name]
6. Contents of the pack and other information

1. What [RH031 trade name] is and what it is used for

[RH031 trade name] contains levonorgestrel, a synthetic female sex hormone-like substance.

[RH031 trade name] prevents pregnancy when you take it after unprotected sex. You can also use it if your usual contraceptive method has failed.

[RH031 trade name] works best if you take it as soon as possible after unprotected sex, usually within 3 days but no more than 5 days after unprotected sex.

[RH031 trade name] is thought to work by:

- stopping your ovaries from releasing an egg or
- preventing sperm from fertilising any egg that may have been released already
- altering the lining of the womb

2. What you need to know before you take [RH031 trade name]

Do not take [RH031 trade name]

- if you are allergic to levonorgestrel or to any of the other ingredients of [RH031 trade name] (listed in section 6)

Warnings and precautions

[RH031 trade name] prevents pregnancy; it does not work if you are already pregnant.

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

You may already be pregnant if:

- your period is more than 5 days late
- your previous period was unusually light or unusually heavy
- you have signs you might be pregnant (e.g. you feel sick or are sick, your breasts are tender)
- you had unprotected sex since your last period and more than 5 days passed between having that sex and taking [RH031 trade name].

If any of these apply, speak with your health care provider and check if you have become pregnant.

If you have unprotected sex in the days after taking [RH031 trade name], it will not protect you from becoming pregnant.

[RH031 trade name] also will not protect you against HIV infection and other sexually transmitted infections.

Ask your health care provider for advice about emergency contraception if you have a disease of your small bowel (such as Crohn's disease) that interferes with the digestion of your food.

[RH031 trade name] may work less well if you are very overweight or weigh more than 70 kg.

Other medicines and [RH031 trade name]

Tell your health care provider if you are taking, have recently taken or might take any other medicines. This is because [RH031 trade name] may affect the way some medicines work. In addition, some medicines may affect the way [RH031 trade name] works. Your health care provider may need to adjust the dose of [RH031 trade name] or you may not be able to take [RH031 trade name] with certain medicines.

- barbiturates and other medicines used to treat epilepsy (for example, carbamazepine, felbamate, oxcarbazepine, phenytoin, primidone, and topiramate)
- some medicines used to treat tuberculosis (for example, rifabutin, rifampicin)
- some medicines to treat HIV infection (for example, efavirenz, ritonavir)
- bosentan, a medicine used to treat high blood pressure in the lungs
- lumacaftor, a medicine used to treat cystic fibrosis
- ciclosporin, a medicine used to suppress the immune system and prevent rejection
- griseofulvin, a medicine used to treat fungal infections
- herbal remedies containing St John's wort (*Hypericum perforatum*)

If any of these apply to you, [RH031 trade name] may not be suitable for you, or other types of emergency contraception may be better for you.

Pregnancy, breast-feeding and fertility

Pregnancy

[RH031 trade name] is not likely to harm your baby if you take it while you are pregnant. If your menstrual period is delayed by more than 5 days or abnormal bleeding occurs at the expected date of menstrual periods after taking [RH031 trade name] or if you suspected you may be pregnant for any reason, see your health care provider for advice and to check that all is well.

Breast-feeding

Very small amounts of the active ingredient of [RH031 trade name] pass into your breast milk. This is not thought to be harmful to the baby, and you can continue to breast-feed your baby.

Fertility

[RH031 trade name] increases the possibility of menstruation disturbances which can sometimes lead to earlier or later ovulation date. These changes can result in modified fertility date, however there are no fertility data in the long term.

Driving and using machines

Your [RH031 trade name] tablet is unlikely to affect your ability to drive a car or use machines. However, if you feel tired or dizzy, do not drive or operate machinery.

Driving and using machines

[RH031 trade name] is not likely to affect your ability to drive or operate machinery.

However, make sure you feel well enough to take on any skilled tasks.

Other ingredients of [RH031 trade name]

This medicine contains lactose. Lactose is a source of glucose and galactose. The small amount of lactose in each dose is unlikely to cause symptoms of lactose intolerance. If, however, you have one of the rare genetic disorders galactosaemia, glucose-galactose intolerance or congenital lactase deficiency you must talk to your health care provider before taking this medicine.

3. How to take [RH031 trade name]

Always use this medicine exactly as described in the leaflet or as your health care provider has told you. Check with your health care provider if you are not sure.

You can use [RH031 trade name] at any time during your menstrual cycle.

Take [RH031 trade name] as soon as possible after you have had unprotected sex (within 3 days but no later than 5 days). Swallow the tablet whole with water. Do not delay taking [RH031 trade name]. It works better the sooner you take a dose after unprotected sex.

The dose of [RH031 trade name] is 1 tablet as soon as possible.

However, the dose of [RH031 trade name] is 2 tablets (at the same time) if you have taken a medicine in the last 4 weeks that makes [RH031 trade name] work less well—see ‘Other medicines and [RH031 trade name]’, above.

If you take more [RH031 trade name] than you should (overdose)

You may feel sick, vomit, or have vaginal bleeding if you take too many tablets at once.

What to do if you are sick (vomit)

- If you are sick (vomit) within 3 hours of taking [RH031 trade name], take another dose straightaway. Talk to your health care provider or family planning clinic immediately for advice and to get another dose.
- If you continue to vomit, talk with your health care provider at once for advice on alternative methods.

After you have taken [RH031 trade name]

After you have taken [RH031 trade name], if you want to have sex, and you are not using the contraceptive pill, you should use condoms or a cap plus spermicide. This is because [RH031 trade name] won't work if you have unprotected sex again, before your next period is due.

Your health care provider can also tell you about longer-term methods of contraception to prevent you from getting pregnant.

If you have any questions about [RH031 trade name] or about emergency contraception, ask your health care provider.

4. Possible side effects

Like all medicines, [RH031 trade name] can cause side effects, but not everybody gets them.

Very common (may affect more than 1 in 10 people):

- Feeling sick (nausea)

- Irregular bleeding until your next period
- Lower abdominal (belly) pain
- Tiredness
- Headache

Common (may affect up to 1 in 10 people):

- Being sick (vomiting). If you are sick, read the section ‘What to do if you are sick (vomit)’.
- Your period might be later or earlier than normal. You might also have some irregular bleeding or spotting until your next period. 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.
- You might have tender breasts, diarrhoea, feel dizzy after taking this medicine.

Very rare (may affect up to 1 in 10,000 people):

- Abdominal pain, rash, urticaria (allergic skin rash), pruritus (dry and itchy skin), swelling of the face, pelvic pain, painful period.

If you think that this medicine affects you in a way that is not mentioned above, tell your health care provider.

Reporting of side effects

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

5. How to store [RH031 trade name]

Keep this medicine out of the sight and reach of children.

Do not store above 30°C. Protect from light. Store the tablet in the blister in the provided carton.

Do not use this medicine after the expiry date stated on the label or carton after ‘EXP’. The expiry date refers to the last day of that month.

Do not use this medicine if you notice description of the visible signs of deterioration that it is different from the description below.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [RH031 trade name] contains

- The active ingredient is levonorgestrel 1.5 mg.
- The other ingredients of [RH031 trade name] are lactose monohydrate, maize starch, povidone, colloidal silicon dioxide and magnesium stearate.

What [RH031 trade name] looks like and contents of the pack

White to off-white, round, uncoated tablets. They are flat on the top and bottom with a flat edge. The tablets have ‘145’ debossed (stamped into) on one side and are plain on the other side.

Clear colourless plastic (PVC/PVdC) on aluminium foil blister cards, each containing 1 tablet. Available in cartons of 1 x 1 tablet.

Supplier and Manufacturer

Supplier

Senador Laboratories Private Limited
Plot 2B & 2C, Biotech Park, Phase II

Manufacturer

Senador Laboratories Private Limited
Plot No. 20 & 21, Pharmez Sarkhej – Bavla

Lalgadi Malakpet, Medchal Malkajgiri
Hyderabad, Telangana – 500101
India
Tel: +91 40 3388 9797
Email: regulatory_senador@senadorlabs.es

National Highway No.8-A Near Village Matoda
Taluka:Sanand, Dist. Ahmedabad 382 213
Gujarat
India

For any information about this medicine, contact the local representative of the supplier.

This leaflet was last revised in July 2025

Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>