

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/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf

[#] Formerly Famy Care Ltd and then Jai Pharma Ltd

Information for the patient

[RH031 trade name][†]
Levonorgestrel

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 has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness seem 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 a synthetic hormone-like substance, levonorgestrel.

[RH031 trade name] prevents about 85% of expected pregnancies when the tablet is taken within 72 hours (3 days) of unprotected sex or if your usual contraceptive method has failed. [RH031 trade name] will not prevent pregnancy in every instance. The tablet is more effective the sooner after unprotected sex it is taken.

[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

[RH031 trade name] prevents pregnancy; it does not work if you are already pregnant. If you have unprotected sex after taking [RH031 trade name], it will not stop you from becoming pregnant.

[RH031 trade name] is not indicated for use before the first menstrual bleeding (menarche).

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

Before you take this medicine, your health care provider may check that you are not already pregnant.

You can use [RH031 trade name] at any time during your menstrual cycle, except if your period is late. If your period is late, you should tell your health care provider.

Do not take [RH031 trade name]

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

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

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- if you are pregnant or suspect you are

Warnings and precautions

If any of the following applies to you, talk to your health care provider before taking [RH031 trade name].

You may already be pregnant if:

- your period is more than 5 days late or if you have unusual bleeding when your next period is due
- you have had unprotected sex more than 72 hours ago, and since your last period

You should 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
- have severe liver problems
- have ever had an ectopic pregnancy (where the baby develops outside the womb)
- have ever had salpingitis (inflammation of the Fallopian tubes)

If you are worried about sexually transmitted diseases

If you did not use a condom (or if it has been torn or slid down) during intercourse, it is possible that you may catch a sexually transmitted disease or HIV infection.

This medicine will not protect you against sexually transmitted diseases, only condoms can do this. Ask your doctor, nurse, family planning clinic or pharmacist for advice if you are worried about this.

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, primidone, phenytoin, carbamazepine, oxcarbazepine, topiramate and felbamate)
- medicines used to treat tuberculosis (for example, rifampicin, rifabutin)
- a treatment for HIV infection (for example, ritonavir);
- a medicine used to treat fungal infections (for example, griseofulvin)
- herbal remedies containing St John's wort (*Hypericum perforatum*)
- cyclosporin, a medicine used to suppress the immune system

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.

Children

[RH031 trade name] must not be used before the first menstruation occurs.

Pregnancy, breast-feeding and fertility

Pregnancy

You should not take this medicine if you are already pregnant. If you have had unprotected sex which was more than 72 hours ago, and since your last period, you may already be pregnant, and the treatment won't work. If your last period was more than 5 days late or was unusually light or unusually heavy or you suspect that you might be pregnant (feeling sick, vomiting, breast tenderness etc.), you should check with your health care provider that you are not already pregnant.

If you do become pregnant even after taking this medicine, it is important that you see your health care provider. There is no evidence that [RH031 trade name] will harm an unborn baby, but your health care

provider 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 or fainting after taking [RH031 trade name], or if you have previously had an ectopic pregnancy, Fallopian tube surgery or pelvic inflammatory disease.

Breast-feeding

Very small amounts of the active ingredient of [RH031 trade name] 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 breast-feeding. In this way you are taking the tablet well before the next feed and reducing the amount of active ingredient your baby may take in with the breast milk.

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.

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.

Take the tablet as soon as possible (but no later than 72 hours) after you have had unprotected sex. Swallow the tablet whole, with water if necessary. Do not delay taking the tablet. The tablet works better the sooner you take it after having unprotected sex.

If you are using one of the medicines that may prevent [RH031 trade name] from working properly (see section above “Other medicines and [RH031 trade name]”) or if you have used one of these medicines in the past 4 weeks, [RH031 trade name] may work less effectively for you. You can therefore, take a double dose of [RH031 trade name] (i.e. 2 tablets taken together at the same time).

How often can you use [RH031 trade name]?

You should only use [RH031 trade name] in an emergency and not as a regular method of contraception. If [RH031 trade name] is used more than once in a menstrual cycle, it is more likely to upset your menstrual cycle (period).

[RH031 trade name] does not work as well as regular methods of contraception. If you need repeated courses of emergency contraception, you should consider long-term methods of contraception.

Use in children and adolescents

This medicine is not recommended for use in children. Very limited data are available in women under 16 years of age.

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

Although there have been no reports of serious harm from taking too many tablets at once, you may feel sick, vomit, or have vaginal bleeding.

What to do if you are sick (vomit)

- If you are sick within 2 hours of taking the tablet, you will need to take another tablet. Talk to your health care provider or family planning clinic immediately for advice and to obtain another tablet.

- If you continue to vomit, you may insert the tablet in your vagina. You will need a second pack to obtain the extra dose. You should also contact your health care provider, as the tablets may not have worked properly.

After you have taken [RH031 trade name]

After you have taken [RH031 trade name], if you want to have sex, and 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.

After you have taken [RH031 trade name], if your next period is more than 5 days late or is unusually light or unusually heavy, you should contact your health care provider as soon as possible. If you do become pregnant even after taking this medicine, it is important that you see your health care provider.

Your health care provider can also tell you about longer-term methods of contraception which are more effective in preventing you from getting pregnant.

If you continue to use regular hormonal contraception such as the contraceptive pill and you do not have a bleed in your pill-free period, see your health care provider to make sure you are not pregnant.

If you have any further questions on the use of this medicine, 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)
- You might have some irregular bleeding until your next period
- You might have lower abdominal 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 different. Most women will have a normal period at the expected time, but some may have their period 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, pruritus, 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 any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. If available, you can also report side effects directly through the national reporting system. By reporting side effects, you can help improve understanding about the safety of 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 carton or blister, after “EXP”. The expiry date refers to the last day of that month.

Do not use this medicine if you notice visible signs of deterioration or 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.
- 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

[RH031 trade name] is a round, white to off-white, uncoated flat tablets debossed ‘145’ on one side and plain on the other side.

Packaging:

PVC/PVdC-Aluminium blister, containing 1 tablet per blister card. One blister card per carton.

Supplier and Manufacturer

Supplier

Mylan Laboratories Limited
Plot No. 564/A/22
Road No. 92 Jubilee Hills
Hyderabad, Telangana - 500096
India

Manufacturer

Mylan Laboratories Limited
Plot No. 20 & 21, Pharmez
Pharmaceutical Special Economic Zone (SEZ)
Sarkhej, Near Matoda Village
Ahmedabad, 382213, Gujarat, India

Email: Imtiyaz.basade@viatris.com

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

This leaflet was last revised in September 2021.

Detailed information on this medicine is available on the World Health Organization (WHO) website:
<https://extranet.who.int/pqweb/medicines>