

Levonorgestrel-1 GH

Consumer Medicine Information (CMI) Summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Levonorgestrel-1 GH?

Levonorgestrel-1 GH contains the active ingredient levonorgestrel. Levonorgestrel-1 GH is used as an emergency contraceptive.

For more information, see Section [1. Why am I using Levonorgestrel-1 GH?](#) in the full CMI.

2. What should I know before I use Levonorgestrel-1 GH?

Do not use if you have ever had an allergic reaction to Levonorgestrel-1 GH or any of the ingredients listed at the end of the CMI.

Talk to your doctor or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Levonorgestrel-1 GH?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Levonorgestrel-1 GH and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Levonorgestrel-1 GH?

- Take one tablet as soon as possible, preferably within 12 hours and no later than 72 hours (3 days) after you have had unprotected sex.

More instructions can be found in Section [4. How do I use Levonorgestrel-1 GH?](#) in the full CMI.

5. What should I know while using Levonorgestrel-1 GH?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Levonorgestrel-1 GH.
Things you should not do	<ul style="list-style-type: none">• Do not take this medicine if you had unprotected intercourse more than 72 hours earlier in the same menstrual cycle.• Do not use this medicine if you are pregnant.
Driving or using machines	<ul style="list-style-type: none">• Do not drive or operate machinery if you feel drowsy or dizzy after using Levonorgestrel-1 GH.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor or pharmacist if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Store the medicine in a cool dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using Levonorgestrel-1 GH?](#) in the full CMI.

6. Are there any side effects?

The most common side effects are tiredness, nausea and vomiting. Other side effects are stomach pain, diarrhoea, dizziness, headache, tender breasts, increased vaginal bleeding and skin reactions.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Levonorgestrel-1 GH

Active ingredient(s): *levonorgestrel*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Levonorgestrel-1 GH. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Levonorgestrel-1 GH.**

Where to find information in this leaflet:

- [1. Why am I using Levonorgestrel-1 GH?](#)
- [2. What should I know before I use Levonorgestrel-1 GH?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Levonorgestrel-1 GH?](#)
- [5. What should I know while using Levonorgestrel-1 GH?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Levonorgestrel-1 GH?

Levonorgestrel-1 GH contains the active ingredient levonorgestrel. Levonorgestrel-1 GH is an emergency contraceptive only. Levonorgestrel-1 GH is not intended as a regular method of contraception.

Levonorgestrel-1 GH is thought to work by:

- stopping your ovaries from releasing an egg;
- preventing sperm from fertilising any egg you may have already released.

It is used to prevent pregnancy when taken within 72 hours (3 days) of unprotected intercourse (sex).

It is estimated that Levonorgestrel-1 GH will prevent 85% of expected pregnancies when you take it within 72 hours of having unprotected sex. It will not prevent a pregnancy every time and is more effective if you take it as soon as possible after unprotected sex.

Levonorgestrel-1 GH will not prevent you from catching sexually transmitted diseases. Ask your doctor or pharmacist if you have any questions about why you are taking Levonorgestrel-1 GH.

Levonorgestrel-1 GH can only prevent you becoming pregnant if you take it within 72 hours of unprotected sex. It does not work if you are already pregnant. If another unprotected intercourse takes place after the use of Levonorgestrel-1 GH (also if this is during the same menstrual cycle), the tablet will not work and there is again the risk of pregnancy.

2. What should I know before I use Levonorgestrel-1 GH?

Warnings

Do not use Levonorgestrel-1 GH if:

- you are allergic to levonorgestrel, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are pregnant.
- you have previously had unprotected intercourse more than 72 hours earlier in the same menstrual cycle (as you may already be pregnant).
- you are experiencing vaginal bleeding for which the reason is not known.
- you have breast cancer.
- the tablets do not look quite right.

Levonorgestrel-1 GH contains lactose. Each Levonorgestrel-1 GH tablet contains 142.5 mg of lactose monohydrate.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product.

Do not take Levonorgestrel-1 GH after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Before you start treatment with Levonorgestrel-1 GH, your doctor or pharmacist should:

- check you are not already pregnant if they suspect you may already have been pregnant before this occurrence of unprotected intercourse.
- ask if you are taking any other medicines (see Section [3. What if I am taking other medicines?](#)).
- ask if you suffer from high blood pressure.
- advise you of the need for careful use of a barrier method of contraception until you have your next period.
- advise you to see your doctor in three weeks' time especially if you have not had a period by then.
- discuss the need for regular contraception.

You should consult your doctor before you take it if:

- you have diabetes mellitus (with kidney, eye or nerve damage, or vascular disease). Diabetes mellitus is a condition in which the body does not produce enough insulin or else the body tissues are not able to use the insulin present. This leads to hyperglycaemia (too much sugar in the blood).
- you have ischaemic heart disease (heart disease caused by reduced blood flow in the blood vessels of the heart muscle).
- you have suffered a stroke.
- you have had breast cancer.
- you are pregnant or think that you may already be pregnant. This medicine will not work if you are already pregnant. If you are already pregnant, Levonorgestrel-1 GH cannot terminate pregnancy. Levonorgestrel-1 GH is not an "abortion pill".

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; or
- you have had unprotected sex more than 72 hours ago and since your last period.

If any of these conditions apply to you it may not be suitable for you to take Levonorgestrel-1 GH.

The use of Levonorgestrel-1 GH is not advised if you:

- have a disease of your gastrointestinal tract (such as Crohn's disease) that interferes with the digestion and absorption of your food.
- have severe liver disease.
- have a history of ectopic pregnancy (where the baby develops somewhere outside the womb).
- have a history of salpingitis (inflammation of the fallopian tubes). A previous ectopic pregnancy or previous infection of the fallopian tubes increases the risk of a new ectopic pregnancy.
- are vomiting or have severe diarrhoea.

Emergency contraception should be taken as soon as possible after unprotected intercourse.

You should only use Levonorgestrel-1 GH in emergencies and not as a regular method of contraception. If Levonorgestrel-1 GH is used more than once in a menstrual cycle, it is less reliable and it is more likely to upset your menstrual cycle (period).

Levonorgestrel-1 GH does not work as well as regular methods of contraception. Your doctor, practice nurse or family planning clinic can tell you about long-term methods of contraception which are more effective in preventing you from getting pregnant

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

You should not take this medicine if you are already pregnant. If you do become pregnant even after taking this medicine, it is important that you see your doctor. Your doctor 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 after taking Levonorgestrel-1 GH or if you have previously had an ectopic pregnancy, fallopian tube surgery or pelvic inflammatory disease.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

The active ingredient of this medicine is excreted into your breast milk. Therefore, it is suggested that you take your tablet immediately after a breastfeeding and avoid breastfeeding for at least 3 days after taking this medicine.

Fertility

Levonorgestrel-1 GH increases the possibility of menstruation disturbances which can sometimes lead to an earlier or later ovulation date resulting in a modified

fertility date. Although there are no fertility data in the long term, after treatment with Levonorgestrel-1 GH a rapid return to fertility is expected and therefore, regular contraception should be continued or initiated as soon as possible after Levonorgestrel-1 GH use.

Children and adolescents

Levonorgestrel-1 GH is not recommended for children. There is only limited information available on Levonorgestrel-1 GH when taken by women aged 14-16 years and no information on its use in younger women or children.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Levonorgestrel-1 GH and affect how it works. Examples of medicines which may interfere with Levonorgestrel-1 GH are:

- medicines used to treat epilepsy (eg. barbiturates, primidone, phenytoin, and carbamazepine);
- medicines used to treat tuberculosis (eg. rifampicin, rifabutin);
- medicines used to treat HIV infection (eg. ritonavir, efavirenz);
- medicines used to treat fungal infections (eg. griseofulvin);
- herbal remedies containing St John's Wort (hypericum perforatum).

Levonorgestrel-1 GH may affect the way other medicines work, including:

- ciclosporin (a medicine which suppresses the immune system).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Levonorgestrel-1 GH.

4. How do I use Levonorgestrel-1 GH?

How much to take

- The dose is one tablet.
- If you vomit within 2 hours of taking the tablet, you should return to your pharmacy, doctor or clinic as the tablet may not be absorbed and you will need to take an additional tablet.

When to take Levonorgestrel-1 GH

- Take the tablet as soon as possible, preferably within 12 hours, and no later than 72 hours (3 days), after you have had unprotected sex. Do not delay taking the tablet. The tablet works best the sooner you take it after having unprotected sex. It can only prevent you becoming pregnant, if you take it within 72 hours of unprotected sex.

- Levonorgestrel-1 GH can be taken at any time in your menstrual cycle assuming you are not already pregnant or think you may be pregnant.
- If you are using one of the medicines that may prevent Levonorgestrel-1 GH from working properly (see Section 3. [What if I am taking other medicines?](#) above) or if you have used one of these medicines in the past 4 weeks, Levonorgestrel-1 GH may not work as well for you.
- If you are already using a regular method of contraception such as the contraceptive pill, you can continue to take this at your regular times.
- If another unprotected intercourse takes place after the use of Levonorgestrel-1 GH (also if this is during the same menstrual cycle), the tablet will not be effective and there is again the risk of pregnancy.
- Speak to a healthcare professional if you are concerned about any problems related to taking emergency contraception.

How to take Levonorgestrel-1 GH

- Swallow the tablet whole with water.
- Do not chew it.

If you use too much Levonorgestrel-1 GH

If you think that you have used too much Levonorgestrel-1 GH, or if a child has taken Levonorgestrel-1 GH tablets, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**); or
- contact your doctor; or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Although there have been no reports of serious harmful effects from taking too many tablets at once, you may feel sick, actually be sick (vomit), or have vaginal bleeding. You should ask your pharmacist, doctor, practice nurse or family planning clinic for advice, especially if you have been sick, as the tablet may not have worked properly.

5. What should I know while using Levonorgestrel-1 GH?

You may experience spotting or vaginal bleeding earlier than expected.

Levonorgestrel-1 GH is only intended as an emergency measure. If you have not already done so you should discuss with your doctor other methods of long term contraception.

Things you should do

You should see your doctor within 3 weeks of taking Levonorgestrel-1 GH to make sure that Levonorgestrel-1 GH has worked.

Call your doctor straight away if you:

- **do not get your period, it is more than 5 days late or is unusually light or unusually heavy, as you may be pregnant.** If Levonorgestrel-1 GH does not work, you could be pregnant. Your doctor will order a pregnancy test.
- **experience severe stomach pain as on rare occasions an ectopic/tubal pregnancy could occur.**

Remind any doctor, dentist or pharmacist you visit that you are using Levonorgestrel-1 GH.

Things you should not do

- You should not breastfeed for 3 days after taking Levonorgestrel-1 GH.
- Do not give Levonorgestrel-1 GH to anyone else.

Where to go for further information

If you require further information you should contact your pharmacist, doctor or clinic.

Additional information is also available at the website: www.emergencycontraception.com.au.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Levonorgestrel-1 GH affects you.

Levonorgestrel-1 GH may make you drowsy or dizzy. Do not drive a car or operate machinery.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Looking after your medicine

- Keep your tablet in a cool, dry place where the temperature stays below 25°C.
- Keep your tablet in the pack until it is time to take it. If you take the tablet out of the pack it will not keep well.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink; or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal <ul style="list-style-type: none">• Nausea.• Vomiting.• Diarrhoea. General <ul style="list-style-type: none">• Tiredness.• Headache.• Dizziness.• Tender breasts. Skin <ul style="list-style-type: none">• Skin reactions.	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Gastrointestinal <ul style="list-style-type: none">• Stomach pain. Reproductive <ul style="list-style-type: none">• Increased vaginal bleeding.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What Levonorgestrel-1 GH contains

Active ingredient (main ingredient)	Levonorgestrel
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Other ingredients (inactive ingredients)	Colloidal anhydrous silica Lactose monohydrate Magnesium stearate Maize starch Povidone
Potential allergens	Lactose monohydrate

Do not take this medicine if you are allergic to any of these ingredients.

What Levonorgestrel-1 GH looks like

Levonorgestrel-1 GH is a white to off-white, round-shaped tablet debossed with 'LV1' on one side and plain on the other side (AUST R 217542).

Levonorgestrel-1 GH contains one blister sheet containing one tablet.

Who distributes Levonorgestrel-1 GH

Generic Health Pty Ltd

Suite 2, Level 2

19-23 Prospect Street

Box Hill, VIC, 3128

Australia

✉ ghinfo@generichealth.com.au

☎ +61 3 9809 7900

🌐 www.generichealth.com.au

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