

LEVONELLE®-1 TABLETS

(levonorgestrel)

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Levonelle-1. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist will have discussed and considered the risks of you taking Levonelle-1 against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Your doctor and pharmacist have more information

Keep this leaflet with the medicine.

You may need to read it again.

WHAT LEVONELLE-1 IS USED FOR

Levonelle-1 is an emergency contraceptive only. Levonelle-1 is not intended as a regular method of contraception.

It is used to prevent pregnancy when taken within 72 hours of unprotected intercourse. It is estimated that Levonelle-1 will prevent 85% of expected pregnancies.

The sooner that you take Levonelle-1 after unprotected intercourse, the more likely it is that the medication will work.

Levonelle-1 is most effective if taken within 72 hours of unprotected intercourse. But remember that the sooner you take it, the more likely it will prevent pregnancy.

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

BEFORE YOU TAKE LEVONELLE-1

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

- Check you are not already pregnant if he/she suspects you may already have been pregnant before this occurrence of unprotected intercourse
- Ask you if you are taking any other medicines (see "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 have severe liver disease.

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

- You have a disease of your gastro-intestinal tract (such as Crohn's disease) that interferes with the digestion and absorption of your food;
- you are vomiting or have severe diarrhoea.

If these conditions apply to you your doctor may recommend a higher dose.

When you must not take it

Do not take Levonelle-1 if:

- 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
- You are allergic to any of the ingredients of the tablets (See "Product Description" below)
- The tablets do not look quite right.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including those purchased from a supermarket or health food store.

Some medicines may prevent Levonelle-1 from working properly or Levonelle-1 may affect the way other medicines work. Examples of medicines which may interfere with Levonelle-1 are:

- Medicines used to treat epilepsy (for example, barbiturates, primidone, phenytoin, and carbamazepine).
- Medicines used to treat tuberculosis (for example, rifampicin, rifabutin).
- A treatment for HIV infection (ritonavir).
- A medicine used to treat fungal infections (griseofulvin).
- Herbal remedies containing St John's Wort (Hypericum perforatum).

HOW TO TAKE LEVONELLE-1

Take the tablet as soon as possible after unprotected intercourse. The sooner that you take the tablet, the more effective the treatment is likely to be. It is best to take it immediately after you receive it. The tablet should be taken no later than 72 hours after intercourse.

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

WHILE TAKING LEVONELLE-1

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.

Things you must do

Tell any doctor or pharmacist who are treating you that you have taken Levonelle-1.

Things you must not do

Do not give Levonelle-1 to anyone else.

What to be careful of

If Levonelle-1 makes you drowsy or dizzy, do not drive a car or operate machinery.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well after you take Levonelle-1.

All medicines have side effects. Often they are not serious but sometimes they can be. You may need medical treatment if you get some side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Common side effects are:

- tiredness
- nausea and vomiting

Some patients have also experienced:

- stomach pain
- diarrhoea
- dizziness
- headache
- tender breasts
- increased vaginal bleeding
- skin reactions.

Other side effects not listed above may also occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

AFTER USING LEVONELLE-1

You should see your doctor within 3 weeks of taking Levonelle-1.

You may experience spotting or vaginal bleeding earlier than expected.

If you do not get your period within 3 weeks of taking the tablets you must see your doctor, as you may be pregnant. If Levonelle-1 does not work, you could be pregnant. Your doctor will order a pregnancy test. If stomach pain is severe you should see your doctor immediately as on rare occasions a tubal pregnancy could occur.

Levonelle-1 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.

You should not breast feed within three days after taking Levonelle-1.

If YOU TAKE TOO MUCH (OVERDOSE)

Telephone your doctor, or the Poisons Information Centre (13 11 26) if you take too many Levonelle-1 tablets, or if a child has taken Levonelle-1.

PRODUCT DESCRIPTION

Levonelle-1 contains one blister sheet containing one flat white tablet. The tablets contains: potato starch, maize starch, silica colloidal anhydrous, magnesium stearate, talc, lactose.

STORAGE

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.

Keep your tablet in a cool, dry place where the temperature stays below 25°C.

Do not store Levonelle-1 or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children can not reach it.

A locked cupboard at least 1½ metres above the ground is a good place to store medicines.

The expiry date is printed on the pack and the foil blister. Do not use Levonelle-1 after this expiry date.

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.

SUPPLIER

The sponsor for Levonelle-1 in Australia is:

Intensive Care Products Pty Ltd

Level 1

Australian Generics House

14 Rodborough Rd

Frenchs Forest NSW 2086

The distributor for Levonelle-1 in Australia is:

Bayer Australia Ltd

ABN 22 000 138 714

875 Pacific Highway

PYMBLE NSW 2073

Australia

Australian Registration Numbers

LEVONELLE -1 - AUST R 149270

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