Levonorgestrel-1 AN Tablets

Levonorgestrel

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Levonorgestrel-1 AN. 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 LEVONORGESTREL-1 AN 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 Levonorgestrel-1 AN is used for

LEVONORGESTREL-1 AN is an emergency contraceptive only. LEVONORGESTREL-1 AN 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

LEVONORGESTREL-1 AN will prevent 85% of expected pregnancies. The sooner that you take LEVONORGESTREL-1 AN after unprotected intercourse, the more likely it is that the medication will work.

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

LEVONORGESTREL-1 AN 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 AN

Before you take Levonorgestrel-1 AN

Before you start treatment with Levonorgestrel-1 AN, 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 LEVONORGESTREL-1 AN.

- 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 LEVONORGESTREL-1 AN 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 LEVONORGESTREL-1 AN 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 LEVONORGESTREL-1 AN from working properly or LEVONORGESTREL-1 AN may affect the way other medicines work. Examples of medicines which may interfere with

- LEVONORGESTREL-1 AN 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 Levonorgestrel-1 AN

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.

LEVONORGESTREL-1 AN is not recommended for children. There is

only limited information available on LEVONORGESTREL-1 AN when taken by women aged 14-16 years and no information on its use in younger women or children.

While taking Levonorgestrel-1 AN

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 Levonorgestrel-1 AN.

Things you must not do

Do not give LEVONORGESTREL-1 AN to anyone else.

Things to be careful of

If LEVONORGESTREL-1 AN 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 Levonorgestrel-1 AN.

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 and 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 taking Levonorgestrel-1 AN

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

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 LEVONORGESTREL-1 AN 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.

LEVONORGESTREL-1 AN 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 Levonorgestrel-1 AN.

If you take too much (Overdose)

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

Product description

LEVONORGESTREL-1 AN contains one blister sheet containing one tablet. Each white tablet contains 1.5 mg of levonorgestrel and the following excipients: lactose, maize starch, povidone, colloidal anhydrous silica and magnesium stearate.

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. Protect from light.

Do not store LEVONORGESTREL-1 AN 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 cannot reach it.

A locked cupboard at least $1\frac{1}{2}$ 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 LEVONORGESTREL-1 AN after this expiry date.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

Supplier

Amneal Pharma Australia Pty Ltd

12 River St South Yarra VIC 3141 The AUST R for LEVONORGESTREL-1 AN is 231121.

This leaflet was prepared in December 2014.