

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about this medicine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is Postella-1 tablet. It contains the active ingredient levonorgestrel.

This medicine is an emergency contraceptive only. It 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 this medicine will prevent 85% of expected pregnancies.

The sooner that you take this medicine after unprotected intercourse, the more likely it is that it will work.

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

This medicine does not prevent you from catching sexually transmitted diseases such as HIV infection (AIDS), chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B, human papilloma virus and syphilis.

Ask your doctor or pharmacist if you have any questions about why this medicine has been recommended for you.

Use in children

This medicine is not recommended for children. There is only limited information available on this medicine when taken by females aged 14-16 years and no information on its use in younger females.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are hypersensitive to, or have had an allergic reaction to, levonorgestrel or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- 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 unexplained vaginal bleeding.
- You have breast cancer.
- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor or pharmacist if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - very high blood pressure
 - diabetes mellitus (with kidney, eye or nerve damage, or vascular disease)
 - ischaemic heart disease (heart disease caused by reduced blood flow in the blood vessels of the heart muscle)
 - a stroke
 - history of breast cancer
 - severe liver disease.

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

The effectiveness of this medicine may be reduced if you have any of the following conditions:

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

If these conditions apply to you, your doctor may recommend taking another tablet.

If you are not sure whether you should take this medicine, talk to your doctor or pharmacist.

3. You are currently pregnant, you think you may be pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant. Do not take this medicine if you have missed your period as you may be pregnant.
4. You are currently breastfeeding or you plan to breastfeed. Levonorgestrel has been identified in breast milk. Women should not breastfeed within 3 days of taking this medicine.

5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop. Some medicines may interact with levonorgestrel. These include:
 - barbiturates (including primidone), phenytoin, and carbamazepine, medicines which may be used to treat epilepsy
 - rifampicin and rifabutin, medicines used to treat tuberculosis
 - ritonavir and efavirenz, medicines used to treat HIV infection
 - griseofulvin, a medicine used to treat fungal infections
 - herbal medicines containing St John's Wort (*Hypericum perforatum*)
 - cyclosporin, a medicine used to prevent organ transplant rejection.

If you are taking any of these you may need a different dose of levonorgestrel or you may need to use a different method of emergency contraception.

Other medicines not listed above may also interact with levonorgestrel.

How to take this medicine

Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.

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.

After taking this medicine

If you vomit within 2 hours of taking this 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.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you have taken this medicine if:

- you are about to be started on any new medicine

- you are pregnant or are planning to become pregnant (you must not take this medicine while pregnant)
- you are breastfeeding or are planning to breastfeed (you should not breastfeed within 3 days of taking this medicine)
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

This medicine 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.

If you have taken this medicine, then it is recommended that you do not have sex again until you get your next period. If you do have sex, you should use a barrier method (e.g. condom, diaphragm, spermicide, cervical cap) until you get your next period.

You should see your doctor within 3 weeks of taking this medicine.

You may experience spotting or vaginal bleeding earlier or later than expected.

If you do not get your period within 3 weeks of taking this medicine you must see your doctor, as you may be pregnant.

If this medicine does not work, you could be pregnant. Your doctor will order a pregnancy test.

If you experience severe stomach pain you should see your doctor immediately as on rare occasions a tubal (ectopic) pregnancy could occur.

Tell any other doctors, dentists and pharmacists who are treating you that you have taken this medicine.

Things you must not do

Do not:

- Take this medicine for any reason other than emergency contraception.
- Give this medicine to anyone else.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor or pharmacist if you notice any of the following:

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

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

Allergic reactions

If you think you are having an allergic reaction to this medicine, tell your doctor or pharmacist immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hayfever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If you do not want to take this medicine or it has passed its expiry date, return it to your pharmacist for disposal.

Product description

What Postella-1 Tablet looks like

1.5 mg tablet - Round, biconvex, white tablet, engraved "C" on one side and "1" on the other side.

Pack size: 1 tablet only.

Ingredients

Each tablet contains 1.5 mg levonorgestrel as the active ingredient.

It also contains the following inactive ingredients:

- microcrystalline cellulose
- lactose monohydrate
- croscarmellose sodium
- poloxamer
- magnesium stearate

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

Postella-1 1.5 mg tablet (blister pack): AUST R 231505.

Sponsor

Apotex Pty Ltd
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This leaflet was last updated in:
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