

Postrelle-1

levonorgestrel

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Postrelle-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 Postrelle-1 against the benefits they expect it will have for you.

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

Your doctor and pharmacist have more information.

Keep this leaflet with your medicine.

You may need to read it again.

What Postrelle-1 is used for

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

It contains the active ingredient levonorgestrel.

It is used to prevent pregnancy when taken within 72 hours of unprotected intercourse. It is estimated that Postrelle-1 will prevent 85% of expected pregnancies. The sooner that you take Postrelle-1 after unprotected intercourse, the more likely it is that the medicine will work.

Postrelle-1 is thought to work by:

- stopping your ovaries from releasing an egg
- preventing sperm from fertilising any eggs you may have already released
- stopping a fertilised egg from attaching itself to your womb lining.

Therefore, Postrelle-1 stops a pregnancy before it is established. It does not work if you are already pregnant.

Postrelle-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 Postrelle-1.

This medicine is not addictive.

Before you take Postrelle-1

When you must not take it

Do not take Postrelle-1 if:

- you are allergic to any medicine containing levonorgestrel, or any of the ingredients listed at the end of this leaflet
- you are pregnant or think you may be 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

Some of the symptoms of an allergic reaction may include

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

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

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Before you start treatment with Postrelle-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 breast feeding (see "After taking Postrelle-1")
- 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

Tell your doctor if you have or have had any of the following medical conditions:

- 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 Postrelle-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 and medicines
- you are vomiting or have severe diarrhoea.

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

If you have not told your doctor about any of the above, tell him/her before you start taking Postrelle-1.

Taking other medicines

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

Some medicines and Postrelle-1 may interfere with each other.

These include:

- medicines used to treat epilepsy (for example, barbiturates, primidone, phenytoin, and carbamazepine).
- medicines used to prevent organ transplant rejection (ciclosporin).
- medicines used to treat tuberculosis (for example, rifampicin, rifabutin).
- medicines used to treat HIV infection (ritonavir, efavirenz).
- a medicine used to treat fungal infections (griseofulvin).
- herbal remedies containing St John's Wort (*Hypericum perforatum*).

These medicines may be affected by Postrelle-1 or may affect how well it works.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Postrelle-1

Take 1 tablet as a single dose as soon as possible after unprotected intercourse and no later than 72 hours (3 days) after intercourse.

The sooner that you take the tablet, the more effective the treatment is likely to be and the more likely that an unexpected pregnancy will be prevented. It is best to take it immediately after you receive it.

Swallow the tablet whole with a full glass of water.

If you are already using a regular method of contraception such as the contraceptive pill, you can continue to take this at your regular time.

Your doctor or pharmacist should advise you to use a barrier contraception method until your next period.

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

You should only take Postrelle-1 in emergencies and not as a regular method of contraception.

If Postrelle-1 is used more than once in a menstrual cycle it is more likely to upset your menstrual cycle.

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Australia: phone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Postrelle-1 or if a child has taken Postrelle-1. 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 or have vaginal bleeding.

While you are taking Postrelle-1

If you vomit within 2 hours of taking the tablet you should return to your pharmacy, doctor or clinic.

You will need to take an additional tablet as the first one may not have been absorbed completely.

Things you must do

Always follow your doctor's or pharmacist's instructions carefully.

Your doctor will be happy to discuss any questions you may have with your medication.

Tell any other doctors, dentists, and pharmacists who are treating you that you have taken Postrelle-1.

Things you must not do

Do not give Postrelle-1 to anyone else.

Things to be careful of

Be careful driving or operating machinery until you know how Postrelle-1 affects you.

This medicine may cause dizziness or light-headedness in some people. Make sure you know how you react to Postrelle-1 before you drive a car, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Postrelle-1.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

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

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

- tiredness
- nausea
- vomiting
- stomach pain
- diarrhoea
- dizziness
- headache
- tender breasts
- increased vaginal bleeding, irregular bleeding or spotting. Most women will have a normal period at the expected time, but some may have their period later or earlier than normal. If your period is more than 5 days late or is unusually light or unusually heavy, or especially painful, you should contact your doctor or pharmacist as soon as possible.

- skin reactions

The above list includes the more common side effects of your medicine. They are usually mild and short-lived but may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing.

These are very serious side effects. You may need urgent medical attention or hospitalisation. All of these side effects are very rare.

Tell your doctor if you notice anything else that is making you feel unwell.

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

Do not hesitate to report any other side effects to your doctor or pharmacist.

After taking Postrelle-1

After taking Postrelle-1, you should use other contraceptive methods if you want to have sex.

Postrelle-1 won't prevent pregnancy from further unprotected sex. Your doctor or pharmacist should advise you to use a barrier contraception method until your next period.

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

You may experience spotting or vaginal bleeding earlier than expected.

You must see your doctor if you do not get your period within 3 weeks of taking Postrelle-1 or your period is unusually light or unusually heavy.

If Postrelle-1 does not work, you could be pregnant. Your doctor will order a pregnancy test.

If you continue to use the contraceptive pill and you do not have a bleed in your pill-free week or while you are taking the non-hormonal tablets, you could be pregnant. Your doctor will order a pregnancy test.

You should see your doctor if you do become pregnant even after taking this medicine.

There is no evidence that Postrelle-1 will harm a baby that develops in your uterus/womb, but your doctor may want to check for an ectopic pregnancy (where the baby develops somewhere outside the womb).

You must see your doctor immediately if you experience severe stomach pain.

On rare occasions an ectopic or tubal pregnancy could occur. This is especially important if you have previously had an

ectopic pregnancy, fallopian tube surgery or pelvic inflammatory disease.

You should discuss with your doctor other methods of long term contraception.

Postrelle-1 is only intended as an emergency measure. Discuss with your doctor other methods of long term contraception which are more effective in preventing you from getting pregnant.

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

Small amounts of levonorgestrel may appear in your breast milk.

Storage

Keep your tablet in the original pack until you need 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 Postrelle-1 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 it 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.

Do not take Postrelle-1 after the expiry date.

The expiry date is printed on the pack and the blister foil.

Disposal

Return any unused or out of date medicine to your pharmacist.

Product description

What it looks like

Postrelle-1: Round, white to off-white, uncoated flat tablet debossed '145' on one side and other side plain.

Available in blister packs containing 1 tablet.

Ingredients

Postrelle-1 contains 1.5 mg of levonorgestrel as the active ingredient.

It also contains the following inactive ingredients:

- povidone
- lactose monohydrate
- maize starch

- magnesium stearate
- silicon dioxide

This medicine does not contain sucrose or gluten. This medicine contains sugars (as lactose).

Supplier

Postrelle-1 is supplied in Australia by:

Alphapharm Pty Ltd

Level 1, 30 The Bond

30 - 34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration number:

Postrelle-1: AUST R 221973

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