POSTRELLE-1

contains the active ingredient 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 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 medication will work. Postrelle-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.

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
- 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 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 gastrointestinal 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.

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).
- a medicine used to help the immune system (cyclosporin).

- 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*).

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 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.

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.

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; or New Zealand: phone 0800 POISON or 0800 764 766) 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.

You may need urgent medical attention.

Symptoms of an overdose may include drowsiness, sleepiness, excessive trembling, excessive muscle stiffness, increased heart rate, very low blood pressure causing fainting or unconsciousness.

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 as the tablet may not be absorbed and you will need to take an additional tablet.

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
- 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.

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

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

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

After taking Postrelle-1

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

Postrelle-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 Postrelle-1.

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 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-anda-half metres above the ground is a good place to store medicines.

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

Product description

What it looks like

Postrelle-1: Round, white to offwhite, 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
- maize starch
- magnesium stearate
- colloidal silicon dioxide

This medicine does not contain sucrose or gluten.

Supplier

Postrelle-1 is supplied in Australia by:

Alphapharm Pty Limited (ABN 93 002 359 739) Level 1, 30 The Bond 30 - 34 Hickson Road Millers Point NSW 2000 Phone: (02) 9298 3999 www.alphapharm.com.au

Medical Information Phone: 1800 028 365

Australian Registration Numbers: Postrelle-1: AUST R 221973

Postrelle-1 is supplied in New Zealand by:

Mylan New Zealand Limited PO Box 11183 Ellerslie

Auckland Free phone: 0800 168 169

This leaflet was prepared in December 2013.

Postrelle-1_cmi\Dec13/00