Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using POSTRELLE-1?

POSTRELLE-1 contains the active ingredient levonorgestrel. POSTRELLE-1 is an emergency contraceptive used to prevent pregnancy when taken within 72 hours of unprotected intercourse.

For more information, see Section <u>1. Why am I using</u> <u>POSTRELLE-1?</u> in the full CMI.

2. What should I know before I use POSTRELLE-1?

Do not use if you have ever had an allergic reaction to POSTRELLE-1 or any of the ingredients listed at the end of the CMI.

Talk to your doctor or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section <u>2. What should I know</u> <u>before I use POSTRELLE-1?</u> in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with POSTRELLE-1 and affect how it works.

A list of these medicines is in Section <u>3. What if I am</u> <u>taking other medicines?</u> in the full CMI.

4. How do I use 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.
- Swallow the tablet whole with a full glass of water. Do not chew.

More instructions can be found in Section <u>4. How do I</u> <u>use POSTRELLE-1?</u> in the full CMI.

5. What should I know while using POSTRELLE-1?

| Things you should do | Remind any doctor, dentist or pharmacist you visit that you are using POSTRELLE-1. |
|--------------------------|--|
| Things you should not do | Do not take this medicine if you had |

| | unprotected intercourse more than 72 hours earlier in the same menstrual cycle. Do not take this medicine if you are pregnant. |
|------------------------------|---|
| Driving or using machines | Be careful driving or operating machinery until you know how POSTRELLE-1 affects you. POSTRELLE-1 may cause dizziness or light- headedness in some people. |
| Drinking alcohol | Tell your doctor or pharmacist if you drink alcohol. |
| Looking after your medicine | Store the medicine in a cool, dry place where the temperature is below 25°C. |

For more information, see Section <u>5. What should I know</u> while using POSTRELLE-1? in the full CMI.

6. Are there any side effects?

The most common side effects are tiredness, nausea and vomiting. Other side effects include stomach pain, diarrhoea, dizziness, headache, tender breasts, increased vaginal bleeding and skin reactions.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

POSTRELLE®-1

Active ingredient(s): levonorgestrel

Consumer Medicine Information (CMI)

This leaflet provides important information about using POSTRELLE-1. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using POSTRELLE-1.

Where to find information in this leaflet:

- 1. Why am I using POSTRELLE-1?
- 2. What should I know before I use POSTRELLE-1?
- 3. What if I am taking other medicines?
- 4. How do I use POSTRELLE-1?
- 5. What should I know while using POSTRELLE-1?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using POSTRELLE-1?

POSTRELLE-1 contains the active ingredient levonorgestrel.

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 (sex).

It is estimated that POSTRELLE-1 will prevent 85% of expected pregnancies when you take it within 72 hours of having unprotected sex. It will not prevent a pregnancy every time and is more effective if you take it as soon as possible after unprotected sex.

POSTRELLE-1 is most effective if taken within 72 hours of unprotected sex. 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

Therefore, POSTRELLE-1 stops a pregnancy before it is established. It does not work if you are already pregnant. If another unprotected intercourse takes place after the use of POSTRELLE-1 (also if this is during the same menstrual cycle), the tablet will not be effective and there is again the risk of pregnancy.

POSTRELLE-1 will not prevent you from catching sexually transmitted diseases.

2. What should I know before I use POSTRELLE-1?

Warnings

Do not use POSTRELLE-1 if:

 you are allergic to levonorgestrel, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

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.
- 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.

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 treatment with POSTRELLE-1, your doctor or pharmacist should:

- discuss if you have allergies to any other medicines, foods, preservatives or dyes.
- check you are not already pregnant if they suspect you may already have been pregnant before this occurrence of unprotected intercourse.
- ask you if you are breast feeding.
- ask you if you are taking any 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 with your doctor before you take POSTRELLE-1 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.
- are pregnant or think that you may already be pregnant. This medicine will not work if you are already pregnant. If you are already pregnant, POSTRELLE-1 cannot terminate pregnancy.
 POSTRELLE-1 is not an "abortion pill". You may already be pregnant if:
 - your period is more than 5 days late, or you have experienced unusual bleeding when your next period is due.
 - you have had unprotected sex more than 72 hours ago and since your last period.

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

The use of POSTRELLE-1 is not advised if you:

- have a disease of your gastrointestinal tract (such as Crohn's disease) that interferes with the digestion and absorption of your food and medicines.
- have severe liver disease.
- have a history of ectopic pregnancy (where the baby develops somewhere outside the womb).
- have a history of salpingitis (inflammation of the fallopian tubes).

A previous ectopic pregnancy or previous infection of the fallopian tubes increases the risk of a new ectopic pregnancy.

• are vomiting or have severe diarrhoea.

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

You should only use POSTRELE-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 less reliable and it is more likely to upset your menstrual cycle (period).

POSTRELLE-1 does not work as well as regular methods of contraception. Your doctor, practice nurse or family planning clinic can tell you about long-term methods of contraception which are more effective in preventing you from getting pregnant.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking POSTRELLE-1.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

You should not take this medicine if you are already pregnant. If you do become pregnant even after taking this medicine, it is important that you see your doctor. Your doctor may want to check that the pregnancy is not ectopic (where the baby develops somewhere outside the womb). This is especially important if you develop severe abdominal pain after taking POSTRELLE-1, or if you have previously had an ectopic pregnancy, fallopian tube surgery, or pelvic inflammatory disease.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

The active ingredient of this medicine is excreted into your breast milk. Therefore, it is suggested that you take your tablet immediately after breastfeeding and avoid nursing at least 3 days after taking this medicine.

Fertility

POSTRELLE-1 increases the possibility of menstruation disturbances which can sometimes lead to an earlier or later ovulation date resulting in a modified fertility date. Although there are no fertility data in the long term, after treatment with POSTRELLE-1, a rapid return to fertility is expected and therefore, regular contraception should be continued or initiated as soon as possible after POSTRELLE-1 use.

Children and adolescents

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.

3. What if I am taking other medicines?

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

Some medicines may interfere with POSTRELLE-1 and affect how it works.

These include:

- medicines used to treat epilepsy (for example, barbiturates, primidone, phenytoin, and carbamazepine).
- 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*).

POSTRELLE-1 may affect the way other medicines work. These include:

 medicines used to prevent organ transplant rejection (ciclosporin).

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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect POSTRELLE-1.

4. How do I use POSTRELLE-1?

How much to take

- Take 1 tablet as a single dose.
- Swallow the tablet whole with a full glass of water. Do not chew.

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.

 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.

When to take POSTRELLE-1

- POSTRELLE-1 should be used 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.
- 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.

- POSTRELLE-1 can be taken at any time in your menstrual cycle, assuming you are not already pregnant or think you may be pregnant.
- If you are using one of the medicines that may prevent POSTRELLE-1 from working properly or if you have used one of these medicines in the past 4 weeks, POSTRELLE-1 may not work as well for you.
- If you are already using a regular method of contraception, such as the contraceptive pill, you can continue to take this at your regular times.
- If another unprotected intercourse takes place after the use of POSTRELLE-1 (also if this is during the same menstrual cycle), the tablet will not be effective and there is again the risk of pregnancy.

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

They may differ for the information contained in this leaflet.

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

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, it is more than 5 days late 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.

If you use too much POSTRELLE-1

If you think that you have used too much POSTRELLE-1, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should 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 (vomit) or have vaginal bleeding. You should ask your pharmacist, doctor, practice nurse or family planning clinic for advice, especially if you have been sick, as the tablet may not have worked properly.

5. What should I know while using POSTRELLE-1?

Things you should 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.

Remind any doctor, dentist or pharmacist you visit that you are using POSTRELLE-1.

Things you should not do

• Do not give POSTRELLE-1 to anyone else.

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: <u>www.emergencycontraception.com.au</u>

Driving or using machines

Be careful before you drive or use any machines or tools until you know how POSTRELLE-1 affects you.

POSTRELLE-1 may cause dizziness or lightheadedness 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.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Looking after your medicine

 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 take POSTRELLE-1 after the expiry date. The expiry date is printed on the pack and the blister foil.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

Less serious side effects

| Less serious side effects | What to do |
|------------------------------|--|
| Gastrointestinal: | Speak to your doctor or pharmacist if you have any of these less serious |
| Nausea | |
| Vomiting | |

| Less serious side effects | What to do |
|------------------------------------|-----------------------|
| Diarrhoea | side effects and they |
| General: | worry you. |
| Tiredness | |
| Headache | |
| Dizziness | |
| Tender breasts | |
| Skin: | |
| Skin reactions | |

Serious side effects

| Serious side effects | What to do |
|--|--|
| Stomach pain Increased vaginal bleeding | Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/reporting-problems</u>. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What POSTRELLE-1 contains

| Active ingredient (main ingredient) | Levonorgestrel |
|--|-----------------------------|
| Other ingredients | Povidone |
| (inactive ingredients) | Lactose monohydrate |
| | Maize starch |
| | Magnesium stearate |
| | Silicon dioxide |
| Potential allergens | Contains sugars as lactose. |

Do not take this medicine if you are allergic to any of these ingredients.

What POSTRELLE-1 looks like

POSTRELLE-1 is a round, white to off-white, uncoated flat tablet debossed '145' on one side and other side plain (AUST R 221973).

Who distributes POSTRELLE-1

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

This leaflet was prepared in August 2024.

POSTRELLE®-1 is a Viatris company trade mark

POSTRELLE-1_cmi\Aug24/00