

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

#### Plan B

#### Levonorgestrel Tablet

Read this carefully before you start taking **Plan B** and each time you buy a new pack.

This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Plan B**.

#### Serious Warnings and Precautions

- **Plan B provides no protection against HIV/AIDS and other sexually transmitted diseases (STDs), such as syphilis, gonorrhoea, chlamydia, and herpes.** If you are worried about whether you may have been infected with HIV/AIDS, or other sexually transmitted diseases, talk to your health professional about your concerns and ask how you can protect yourself in the future.
- **If your period is delayed more than 1 week, you should contact your doctor and have a pregnancy test done.**

#### What is Plan B used for?

- **Plan B is an emergency or backup contraceptive.** Plan B can prevent pregnancy after a contraceptive accident (such as a broken condom) or when no form of birth control was used. Treatment is **most** effective if used in the first 72 hours (3 days) following unprotected sex. The sooner it is taken, the better it works.

**Plan B will not work when a woman is pregnant. Plan B cannot terminate an existing pregnancy.** Although, there is no scientific evidence that Plan B would harm a developing embryo, women who are already pregnant should not use this product.

- **Plan B should not be used in place of regular contraception.** It does not work as well as most other contraceptives used correctly.

#### How does Plan B work?

**Plan B** acts as an emergency contraceptive by preventing the release of an egg from the ovary. **Plan B** is not effective once a pregnancy has started, that is once the fertilized egg has attached to the wall of the uterus. **Plan B** does not cause an abortion.

Plan B can be used following any unprotected act of sexual intercourse, including:

- When no contraceptive has been used
- When a contraceptive method may have failed, including:
  - Condom rupture, slippage, or misuse

- Diaphragm or cap dislodgment, breakage, or early removal
- Failure to withdraw before ejaculation
- Miscalculation of the fertile period by women practising periodic abstinence
- IUD expulsion
- Missed oral contraceptives
- A delay in starting a new packet of oral contraceptives
- A delay in getting a scheduled contraceptive injection
- In cases of sexual assault (rape)

#### **What are the ingredients in Plan B?**

Medicinal ingredients: levonorgestrel

Non-medicinal ingredients: colloidal silicon dioxide, potato starch, magnesium stearate, talc, corn starch, and lactose monohydrate.

#### **Plan B comes in the following dosage forms:**

The package contains one tablet, containing 1.5 mg of levonorgestrel. The tablet is white, round and marked G00.

#### **Do not use Plan B if:**

- you have a confirmed or suspected pregnancy
- you are allergic to Levonorgestrel or to any ingredients in the formulation (see non-medicinal ingredients below)
- you have abnormal vaginal bleeding

#### **To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Plan B. Talk about any health conditions or problems you may have, including if you:**

- have unusual vaginal bleeding that has not yet been diagnosed
- have known or suspected breast cancer
- have active liver disease or tumour
- have diabetes
- have hypertension (a heart condition)
- are pregnant or breast feeding

#### **Other warnings you should know about:**

**Plan B is for Emergency Contraceptive Use Only and should not be used on a regular basis. Plan B is not as effective in preventing pregnancy as most other birth control methods (e.g., oral contraceptive pills, IUDs, implants, or condoms, etc.). It should not be relied on for routine birth control by sexually active women.**

Plan B provides only short-term protection against pregnancy. Sexual activity that takes place later can still result in pregnancy if no contraceptive is used. You must abstain from sex or use another barrier method of birth control until your next normal period to make sure you do not get pregnant.

In all women, emergency contraception should be taken as soon as possible after unprotected intercourse. There is some data that levonorgestrel may be less effective with increasing body weight or body mass index (BMI), but these data were limited and inconclusive. If you have any questions regarding this, please consult with a health care professional.

Tell your doctor if you have taken Plan B within 3 days of a Pap test, as it may affect your results.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with Plan B:**

- anti-HIV drugs (efavirenz, ritonavir)
- anticonvulsant drugs (phenytoin, carbamazepine, primidone, phenobarbital)
- antibiotics (ampicillin, cotrimoxazole, tetracycline, temafloxacin, clarithromycin)
- rifampicin
- rifabutin
- griseofulvin
- *Hypericum perforatum* (St. John's wort)
- ulipristal acetate

If your period is delayed more than 1 week and you were taking any of these medications, you should contact your doctor or pharmacist and have a pregnancy test done.

**How to take Plan B:**

- **Usual dose**  
Plan B can prevent pregnancy if the tablet is taken within 72 hours (3 days) and preferably within 12 **hours after a contraceptive accident or unprotected sex (sex without birth control)**. Do not delay starting treatment. Plan B is more effective the sooner you start after unprotected intercourse.

Plan B can be taken with a glass of water.

If you vomit within 2 hours of taking Plan B, call your doctor or pharmacist as you might need another dose.

**Important:** If more than 72 hours (3 days) have passed since unprotected sex occurred, Plan B may not be effective. See your health professional as soon as possible to discuss other options.

Although the risk of pregnancy is highest in the middle of the menstrual cycle (possibly as early as day 10 after the beginning of your last period), pregnancy can occur at other times during the menstrual cycle. Plan B can be administered anytime during your monthly cycle if you are worried about an unwanted pregnancy.

The treatment does not bring on menstruation. You may experience spotting a few days after taking Plan B, but this is not a period. Your next menstrual period should come on time (or a few days early or late). If your period is delayed more than a week or if you have any other cause for concern, talk to a health professional. More than occasional use (more than once in a menstrual cycle or more than once a month) may upset your menstrual cycle (period).

If you are sexually active and do not wish to become pregnant, you should use a reliable method of contraception on a regular basis. If you want more information about regular contraceptives or if you are having trouble using a method, ask your health professional for help in choosing a method

that works for you.

**Overdose:**

Symptoms of overdose may include nausea, vomiting, vaginal bleeding, and may lead to menstrual cycle disturbances.

If you think you, or a person you are caring for, have taken too much Plan B, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

**What are possible side effects from using Plan B?**

These are not all the possible side effects you may have when taking Plan B. If you experience any side effects not listed here, tell your healthcare professional.

Plan B can cause temporary side effects in some women. These side effects generally do not last more than 24 hours. Common side effects include:

- **Nausea:** This occurs in about 14 to 23% of women taking Plan B
- **Abdominal pain:** This occurs in about 18% of women taking Plan B
- **Fatigue:** This occurs in about 17% of women taking Plan B
- **Headache:** This occurs in about 17% of women taking Plan B
- **Dizziness:** This occurs in about 11% of women taking Plan B
- **Breast tenderness:** This occurs in about 11% of women taking Plan B
- **Vomiting:** This occurs in about 6% of women taking Plan B
- **Diarrhea:** This occurs in about 5% of women taking Plan B
- **Irregular menstrual bleeding:** Some women may experience spotting after taking Plan B. The majority of women will have their next menstrual period at the expected time or early. When Plan B is used repeatedly (more than once in a menstrual cycle, or more than occasional once a month use), menstrual changes may occur, including a shorter or longer cycle and a heavier or lighter period than normal.

Less common side effects: Migraine or severe headache, lower abdominal pain, painful menstruation, and vaginal discharge. If the symptoms continue for more than 48 hours or are severe, see your health professional.

**Delayed menstrual period:** If your period is delayed more than 1 week, you should contact your doctor or pharmacist and have a pregnancy test done.

These are not all the possible side effects you may have when taking Plan B. If you experience any side effects not listed here, tell your healthcare professional.

**Serious side effects and what to do about them**

Serious adverse drug reactions following the use of Plan B are rare.

Serious side effects and what to do about them			
Symptom/effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>COMMON</b>			
Vaginal hemorrhage: excess bleeding	X		
<b>RARE</b>			
Allergic reaction: itching and rash	X		X
Tubal (ectopic) pregnancy: cramping or severe pain in your stomach or belly prior to your next normal period		X	
Uterine hemorrhage: excess bleeding		X	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting ([canada.ca/drug-device-reporting](https://canada.ca/drug-device-reporting)) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

Store Plan B tablet between 15°C and 30°C (59-86 °F). Protect from high humidity. Keep out of reach and sight of children.

### If you want more information about Plan B:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website [www.planb.ca](http://www.planb.ca), or by calling 1-888-919 0782.

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