

**PART III: CONSUMER INFORMATION
PLAN B®**

Levonorgestrel Tablet 1.5 mg

This leaflet is part III of a three-part "Product Monograph" published when Plan B® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Plan B®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is 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.

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.

What it does:

Plan B® acts as an emergency contraceptive by preventing the release of an egg from the ovary, or preventing sperm and egg from uniting. In addition, Plan B® may prevent the fertilized egg from attaching to the wall of the uterus. 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)

When it should not be used:

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-medical ingredients below)
- you have abnormal vaginal bleeding

What the medicinal ingredient is:

Levonorgestrel

What the non-medical ingredients are:

Colloidal silicon dioxide, potato starch, magnesium stearate, talc, cornstarch and lactose monohydrate.

What dosage forms it comes in:

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

WARNINGS AND PRECAUTIONS

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.**

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.

BEFORE you use Plan B[®], talk to your doctor or pharmacist if you have now or have previously had any of the following conditions:

- Unusual vaginal bleeding that has not yet been diagnosed
- Known or suspected breast cancer
- Active liver disease or tumour
- You have diabetes
- You have hypertension (a heart condition)
- You are pregnant or breast feeding

INTERACTIONS WITH THIS MEDICATION

Before you use Plan B[®], talk to your doctor or pharmacist if you are taking any of the following drugs:

Drugs that may decrease the efficacy of Plan B[®] include:

- 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.

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

PROPER USE OF THIS MEDICATION

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:

In case of drug overdose, contact a health care professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

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

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Call your doctor immediately if the following symptoms and signs of serious adverse effects occur:

- Itching and rash
- Cramping or severe pain in your stomach or belly prior to your next normal period, since this can be a warning sign of tubal (ectopic) pregnancy – a serious medical problem.
- Uterine hemorrhage
- Vaginal hemorrhage

HOW TO STORE IT

Store Plan B[®] tablet between 15°C and 30°C (59-86 °F).

Protect from high humidity (such as damp storage conditions).

Keep out of reach of children.

Reporting Side Effects

You can help improve the safe use of health products for Canadian by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect:
<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>;
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada,
Postal Locator 0701E
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>).

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.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found by contacting the distributor, Paladin Labs Inc., at: 1-888-867-7426 or at www.paladinlabs.com.

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Last revised: April 26, 2018.

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