

# plan B<sup>®</sup>

Levonorgestrel Tablets 0.75 mg

This leaflet is part III of a three-part "Product Monograph" published when Plan B<sup>®</sup> 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<sup>®</sup>. Contact your doctor or pharmacist if you have any questions about the drug.

## ABOUT THIS MEDICATION

### What the medication is used for:

**Plan B<sup>®</sup> is a backup contraceptive.**

Plan B<sup>®</sup> 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<sup>®</sup> cannot terminate an existing pregnancy.** Although there is no scientific evidence that Plan B<sup>®</sup> would harm a developing embryo, women who are already pregnant should not use this product.

**Plan B<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> may prevent the fertilized egg from attaching to the wall of the uterus. Plan B<sup>®</sup> is not effective once a pregnancy has started, that is once the fertilized egg has attached to the wall of the uterus. Plan B<sup>®</sup> does not cause an abortion.

Plan B<sup>®</sup> 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:

Plan B<sup>®</sup> is not recommended for use if:

- you have a confirmed pregnancy
- you are allergic to it, or to any of the components of its formulation (for list of components, see the section "what the nonmedicinal ingredients are")
- you have abnormal vaginal bleeding

### What the medicinal ingredient is:

Levonorgestrel

### What the nonmedicinal ingredients are:

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

### What dosage forms it comes in:

The package contains two tablets, each containing 0.75 mg of levonorgestrel. The tablet is white, round, and marked INOR.

## WARNINGS AND PRECAUTIONS

### Serious Warnings and Precautions

- **Plan B<sup>®</sup> 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 you do not get your period in the next 21 days after using Plan B<sup>®</sup>, you should contact your doctor and have a pregnancy test done.**

Plan B<sup>®</sup> is for Emergency Contraceptive Use Only and should not be used on a regular basis.

Plan B<sup>®</sup> 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. 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.

**BEFORE** you use Plan B<sup>®</sup>, 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 tumor
- You have diabetes
- You are using any other medication
- You have hypertension (a heart condition)
- You are breast feeding

## INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with Plan B<sup>®</sup> include:

Anticonvulsant drugs (phenytoin, carbamazepine), antibiotics (ampicillin, cotrimoxazole, tetracycline, temafloxacin, clarithromycin), rifampicin, acetaminophen.

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

## PROPER USE OF THIS MEDICATION

### Usual dose:

**Plan B<sup>®</sup> can prevent pregnancy if the 2 tablets are taken together within 72 hours (3 days) after a contraceptive accident or unprotected sex (sex without birth**

**control).** Plan B<sup>®</sup> can be taken with a glass of water. If you vomit less than 1 hour after taking Plan B<sup>®</sup>, call your healthcare professional as you might need another dose.

You should not delay starting treatment. Plan B<sup>®</sup> is more effective the sooner you start taking the tablets after unprotected intercourse.

**Important:** If more than 72 hours (3 days) have passed since unprotected sex occurred, Plan B<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>, 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).

**Plan B<sup>®</sup> is not as effective in preventing pregnancy as the use of 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.**

### Overdose:

Contact your local poison control center or emergency room immediately. 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<sup>®</sup> 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<sup>®</sup>.
- **Vomiting:** This occurs in about 6% of women taking Plan B<sup>®</sup>.
- **Irregular menstrual bleeding:** Some women may experience spotting after taking Plan B<sup>®</sup>. The majority of women will have their next menstrual period at the expected time or early. When Plan B<sup>®</sup> 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: Breast tenderness, headache, dizziness, fatigue, lower abdominal pain, and diarrhoea. If the symptoms continue for more than 48 hours or are severe, see your health professional.

## 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
- Migraine or severe headache
- If you vomit in less than 1 hour after taking the tablet, as you may need to take another dose
- If your period is delayed more than 1 week, in case you might be pregnant.

## HOW TO STORE IT

Store Plan B<sup>®</sup> tablets 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 SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345  
toll-free fax: 866-678-6789

By email: [cadrmpp@hc-sc.gc.ca](mailto:cadrmpp@hc-sc.gc.ca)

By regular mail:  
National AR Centre  
Marketed Health Products Safety and Effectiveness  
Information Division  
Marketed Health Products Directorate  
Tunney's Pasture, AL 0701C  
Ottawa ON K1A 0K9

*NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.*

## MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor, Paladin Labs Inc., at: 1-888-550-6060 [www.paladinlabs.com](http://www.paladinlabs.com)

This leaflet was prepared by:

Paladin Labs Inc.  
Montreal, Canada H4P 2T4  
Last revised: March 2007