

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-998**

**LABELING**

**HIGHLIGHTS OF PRESCRIBING INFORMATION**

These highlights do not include all the information needed to use Plan B One-Step safely and effectively. See full prescribing information for Plan B One-Step.

Plan B One-Step (levonorgestrel) tablet, 1.5 mg, for oral use

Initial U.S. Approval: 1982

-----INDICATIONS AND USAGE-----

Plan B One-Step is a progestin-only emergency contraceptive indicated for prevention of pregnancy following unprotected intercourse or a known or suspected contraceptive failure. Plan B One-Step is available only by prescription for women younger than age 17 years, and available over the counter for women 17 years and older. Plan B One-Step is not intended for routine use as a contraceptive. (1)

-----DOSAGE AND ADMINISTRATION-----

One tablet taken orally as soon as possible within 72 hours after unprotected intercourse. Efficacy is better if the tablet is taken as soon as possible after unprotected intercourse. (2)

-----DOSAGE FORMS AND STRENGTHS-----

1.5 mg tablet (3)

-----CONTRAINDICATIONS-----

Known or suspected pregnancy (4)

-----WARNINGS AND PRECAUTIONS-----

- Ectopic pregnancy: Women who become pregnant or complain of lower abdominal pain after taking Plan B One-Step should be evaluated for ectopic pregnancy. (5.1)

- Plan B One-Step is not effective in terminating an existing pregnancy. (5.2)
- Effect on menses: Plan B One-Step may alter the next expected menses. If menses is delayed beyond 1 week, pregnancy should be considered. (5.3)
- STI/HIV: Plan B One-Step does not protect against STI/HIV. (5.4)

-----ADVERSE REACTIONS-----

The most common adverse reactions ( $\geq 10\%$ ) in clinical trials included heavier menstrual bleeding (31%), nausea (14%), lower abdominal pain (13%), fatigue (13%), headache (10%), and dizziness (10%). (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Barr Laboratories at 1-800-330-1271 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

-----DRUG INTERACTIONS-----

Drugs or herbal products that induce certain enzymes, such as CYP3A4, may decrease the effectiveness of progestin-only pills. (7)

-----USE IN SPECIFIC POPULATIONS-----

- Nursing Mothers: Small amounts of progestin pass into the breast milk of nursing women taking progestin-only pills for long-term contraception, resulting in detectable steroid levels in infant plasma. (8.3)
- Plan B One-Step is not intended for use in premenarcheal (8.4) or postmenopausal females (8.5).

See 17 for PATIENT COUNSELING INFORMATION.

Revised 7/2009

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**FULL PRESCRIBING INFORMATION****1 INDICATIONS AND USAGE**

Plan B<sup>®</sup> One-Step is a progestin-only emergency contraceptive indicated for prevention of pregnancy following unprotected intercourse or a known or suspected contraceptive failure. To obtain optimal efficacy, the tablet should be taken as soon as possible within 72 hours of intercourse.

Plan B One-Step is available only by prescription for women younger than age 17 years, and available over the counter for women 17 years and older.

Plan B One-Step is not indicated for routine use as a contraceptive.

**2 DOSAGE AND ADMINISTRATION**

Take Plan B One-Step orally as soon as possible within 72 hours after unprotected intercourse or a known or suspected contraceptive failure. Efficacy is better if the tablet is taken as soon as possible after unprotected intercourse. Plan B One-Step can be used at any time during the menstrual cycle.

If vomiting occurs within two hours of taking the tablet, consideration should be given to repeating the dose.

**3 DOSAGE FORMS AND STRENGTHS**

The Plan B One-Step tablet is supplied as an almost white, round tablet containing 1.5 mg of levonorgestrel and is marked G00 on one side.

**4 CONTRAINDICATIONS**

Plan B One-Step is contraindicated for use in the case of known or suspected pregnancy.

**5 WARNINGS AND PRECAUTIONS****5.1 Ectopic Pregnancy**

Ectopic pregnancies account for approximately 2% of all reported pregnancies. Up to 10% of pregnancies reported in clinical studies of routine use of progestin-only contraceptives are ectopic.

A history of ectopic pregnancy is not a contraindication to use of this emergency contraceptive method. Healthcare providers, however, should consider the possibility of an ectopic pregnancy in women who become pregnant or complain of lower abdominal pain after taking Plan B One-Step. A follow-up physical or pelvic examination is recommended if there is any doubt concerning the general health or pregnancy status of any woman after taking Plan B One-Step.

**5.2 Existing Pregnancy**

Plan B One-Step is not effective in terminating an existing pregnancy.

**5.3 Effects on Menses**

Some women may experience spotting a few days after taking Plan B One-Step. Menstrual bleeding patterns are often irregular among women using progestin-only oral contraceptives and women using levonorgestrel for postcoital and emergency contraception.

If there is a delay in the onset of expected menses beyond 1 week, consider the possibility of pregnancy.

**5.4 STI/HIV**

Plan B One-Step does not protect against HIV infection (AIDS) or other sexually transmitted infections (STIs).

**5.5 Physical Examination and Follow-up**

A physical examination is not required prior to prescribing Plan B One-Step. A follow-up physical or pelvic examination is recommended if there is any doubt concerning the general health or pregnancy status of any woman after taking Plan B One-Step.

**5.6 Fertility Following Discontinuation**

A rapid return of fertility is likely following treatment with Plan B One-Step for emergency contraception; therefore, routine contraception should be continued or initiated as soon as possible following use of Plan B One-Step to ensure ongoing prevention of pregnancy.

**6 ADVERSE REACTIONS****6.1 Clinical Trials Experience**

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Plan B One-Step was studied in a randomized, double-blinded multicenter clinical trial. In this study, all women who had received at least one dose of study medication were included in the safety analysis: 1,379 women in the Plan B One-Step group, and 1,377 women in the Plan B group (2 doses of 0.75 mg levonorgestrel taken 12 hours apart). The mean age of women given Plan B One-Step was 27 years. The racial demographic of those enrolled was 54% Chinese, 12% Other Asian or Black, and 34% were Caucasian in each treatment group. 1.6% of women in the Plan B One-Step group and 1.4% in Plan B group were lost to follow-up.

The most common adverse events (>10%) in the clinical trial for women receiving Plan B One-Step included heavier menstrual bleeding (30.9%), nausea (13.7%), lower abdominal pain (13.3%), fatigue (13.3%), and headache (10.3%). Table 1 lists those adverse events that were reported in > 4% of Plan B One-Step users.

Table 1. Adverse Events in &gt; 4% of Women, by % Frequency

Most Common Adverse Events (MedDRA)	Plan B One-Step N = 1359 (%)
Heavier menstrual bleeding	30.9
Nausea	13.7
Lower abdominal pain	13.3
Fatigue	13.3
Headache	10.3
Dizziness	9.6
Breast tenderness	8.2
Delay of menses (> 7 days)	4.5

## 6.2 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of Plan B (2 doses of 0.75 mg levonorgestrel taken 12 hours apart). Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

### *Gastrointestinal Disorders*

Abdominal Pain, Nausea, Vomiting

### *General Disorders and Administration Site Conditions*

Fatigue

### *Nervous System Disorders*

Dizziness, Headache

### *Reproductive System and Breast Disorders*

Dysmenorrhea, Irregular Menstruation, Oligomenorrhea, Pelvic Pain

## 7 DRUG INTERACTIONS

Drugs or herbal products that induce enzymes, including CYP3A4, that metabolize progestins may decrease the plasma concentrations of progestins, and may decrease the effectiveness of progestin-only pills. Some drugs or herbal products that may decrease the effectiveness of progestin-only pills include:

- barbiturates
- bosentan
- carbamazepine
- felbamate
- griseofulvin
- oxcarbazepine
- phenytoin
- rifampin
- St. John's wort
- topiramate

Significant changes (increase or decrease) in the plasma levels of the progestin have been noted in some cases of co-administration with HIV protease inhibitors or with non-nucleoside reverse transcriptase inhibitors.

Consult the labeling of all concurrently used drugs to obtain further information about interactions with progestin-only pills or the potential for enzyme alterations.

## 8 USE IN SPECIFIC POPULATIONS

### 8.1 Pregnancy

Many studies have found no harmful effects on fetal development associated with long-term use of contraceptive doses of oral progestins. The few studies of infant growth and development that have been conducted with progestin-only pills have not demonstrated significant adverse effects.

### 8.3 Nursing Mothers

In general, no adverse effects of progestin-only pills have been found on breastfeeding performance or on the health, growth, or development of the infant. However, isolated post-marketing cases of decreased milk production have been reported. Small amounts of progestins pass into the breast milk of nursing mothers taking progestin-only pills for long-term contraception, resulting in detectable steroid levels in infant plasma.

#### 8.4 Pediatric Use

Safety and efficacy of progestin-only pills for long-term contraception have been established in women of reproductive age. Safety and efficacy are expected to be the same for postpubertal adolescents less than 17 years and for users 17 years and older. Use of Plan B One-Step emergency contraception before menarche is not indicated.

#### 8.5 Geriatric Use

This product is not intended for use in postmenopausal women.

#### 8.6 Race

No formal studies have evaluated the effect of race. However, clinical trials demonstrated a higher pregnancy rate in Chinese women with both Plan B and the Yuzpe regimen (another form of emergency contraception). There was a non-statistically significant increased rate of pregnancy among Chinese women in the Plan B One-Step trial. The reason for this apparent increase in the pregnancy rate with emergency contraceptives in Chinese women is unknown.

#### 8.7 Hepatic Impairment

No formal studies were conducted to evaluate the effect of hepatic disease on the disposition of Plan B One-Step.

#### 8.8 Renal Impairment

No formal studies were conducted to evaluate the effect of renal disease on the disposition of Plan B One-Step.

### 9 DRUG ABUSE AND DEPENDENCE

Levonorgestrel is not a controlled substance. There is no information about dependence associated with the use of Plan B One-Step.

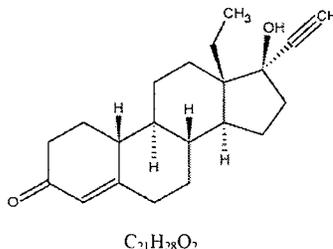
### 10 OVERDOSAGE

There are no data on overdosage of Plan B One-Step, although the common adverse event of nausea and associated vomiting may be anticipated.

### 11 DESCRIPTION

The Plan B One-Step tablet contains 1.5 mg of a single active steroid ingredient, levonorgestrel [18,19-Dinorpregn-4-en-20-yn-3-one-13-ethyl-17-hydroxy-, (17 $\alpha$ )-(-)-], a totally synthetic progestogen. The inactive ingredients are colloidal silicon dioxide, corn starch, lactose monohydrate, magnesium stearate, potato starch, and talc.

Levonorgestrel has a molecular weight of 312.45, and the following structural and molecular formulas:



### 12 CLINICAL PHARMACOLOGY

#### 12.1 Mechanism of Action

Emergency contraceptive pills are not effective if a woman is already pregnant. Plan B One-Step is believed to act as an emergency contraceptive principally by preventing ovulation or fertilization (by altering tubal transport of sperm and/or ova). In addition, it may inhibit implantation (by altering the endometrium). It is not effective once the process of implantation has begun.

#### 12.3 Pharmacokinetics

##### *Absorption*

Following a single dose administration of Plan B One-Step in 30 women under fasting conditions, maximum plasma concentrations of levonorgestrel of 19.1 ng/mL were reached at 1.7 hours. See Table 2.

**Table 2. Pharmacokinetic Parameter Values Following Single Dose Administration of Plan B One-Step (levonorgestrel) tablet 1.5 mg to 30 Healthy Female Volunteers under Fasting Conditions**

	Mean ( $\pm$ SD)				
	C <sub>max</sub> (ng/mL)	AUC <sub>0-t</sub> (ng·hr/mL)*	AUC <sub>0-∞</sub> (ng·hr/mL)*	T <sub>max</sub> (hr)**	t <sub>1/2</sub> (hr)
Levonorgestrel	19.1 ( 9.7)	294.8 ( 208.8)	307.5 ( 218.5)	1.7 (1.0-4.0)	27.5 ( 5.6)

C<sub>max</sub> = maximum concentration

AUC<sub>0-t</sub> = area under the drug concentration curve from time 0 to time of last determinable concentration

AUC<sub>0-∞</sub> = area under the drug concentration curve from time 0 to infinity

T<sub>max</sub> = time to maximum concentration

t<sub>1/2</sub> = elimination half life

\* N=29

\*\* median (range)

**Effect of Food:** The effect of food on the rate and the extent of levonorgestrel absorption following single oral administration of Plan B One-Step has not been evaluated.

#### *Distribution*

The apparent volume of distribution of levonorgestrel is reported to be approximately 1.8 L/kg. It is about 97.5 to 99% protein-bound, principally to sex hormone binding globulin (SHBG) and, to a lesser extent, serum albumin.

#### *Metabolism*

Following absorption, levonorgestrel is conjugated at the 17 $\beta$ -OH position to form sulfate conjugates and, to a lesser extent, glucuronide conjugates in plasma. Significant amounts of conjugated and unconjugated 3 $\alpha$ , 5 $\beta$ -tetrahydrolevonorgestrel are also present in plasma, along with much smaller amounts of 3 $\alpha$ , 5 $\alpha$ -tetrahydrolevonorgestrel and 16 $\beta$ hydroxylevonorgestrel. Levonorgestrel and its phase I metabolites are excreted primarily as glucuronide conjugates. Metabolic clearance rates may differ among individuals by several-fold, and this may account in part for the wide variation observed in levonorgestrel concentrations among users.

#### *Excretion*

About 45% of levonorgestrel and its metabolites are excreted in the urine and about 32% are excreted in feces, mostly as glucuronide conjugates.

#### **Specific Populations**

##### *Pediatric*

This product is not intended for use in the premenarcheal population, and pharmacokinetic data are not available for this population.

##### *Geriatric*

This product is not intended for use in postmenopausal women, and pharmacokinetic data are not available for this population.

##### *Race*

No formal studies have evaluated the effect of race. However, clinical trials demonstrated a higher pregnancy rate in Chinese women with both Plan B and the Yuzpe regimen (another form of emergency contraception). There was a non-statistically significant increased rate of pregnancy among Chinese women in the Plan B One-Step trial. The reason for this apparent increase in the pregnancy rate with emergency contraceptives in Chinese women is unknown [see *USE IN SPECIFIC POPULATIONS (8.6)*].

##### *Hepatic Impairment*

No formal studies were conducted to evaluate the effect of hepatic disease on the disposition of Plan B One-Step.

##### *Renal Impairment*

No formal studies were conducted to evaluate the effect of renal disease on the disposition of Plan B One-Step.

#### **Drug-Drug Interactions**

No formal drug-drug interaction studies were conducted with Plan B One-Step [see *DRUG INTERACTIONS (7)*].

## 13 NONCLINICAL TOXICOLOGY

### 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

**Carcinogenicity:** There is no evidence of increased risk of cancer with short-term use of progestins. There was no increase in tumorigenicity following administration of levonorgestrel to rats for 2 years at approximately 5  $\mu$ g/day, to dogs for 7 years at up to 0.125 mg/kg/day, or to rhesus monkeys for 10 years at up to 250  $\mu$ g/kg/day. In another 7 year dog study, administration of levonorgestrel at 0.5 mg/kg/day did increase the number of mammary adenomas in treated dogs compared to controls. There were no malignancies.

Genotoxicity: Levonorgestrel was not found to be mutagenic or genotoxic in the Ames Assay, in vitro mammalian culture assays utilizing mouse lymphoma cells and Chinese hamster ovary cells, and in an in vivo micronucleus assay in mice.

Fertility: There are no irreversible effects on fertility following cessation of exposures to levonorgestrel or progestins in general.

## 14 CLINICAL STUDIES

A double-blind, randomized, multicenter, multinational study evaluated and compared the efficacy and safety of three different regimens for emergency contraception. Subjects were enrolled at 15 sites in 10 countries; the racial/ethnic characteristics of the study population overall were 54% Chinese, 34% Caucasian, and 12% Black or Asian (other than Chinese). 2,381 healthy women with a mean age of 27 years, who needed emergency contraception within 72 hours of unprotected intercourse were involved and randomly allocated into one of the two levonorgestrel groups. A single dose of 1.5 mg of levonorgestrel (Plan B One-Step) was administered to women allocated into group 1. Two doses of 0.75 mg levonorgestrel 12 hours apart (Plan B) were administered to women in group 2. In the Plan B One-Step group, 16 pregnancies occurred in 1,198 women and in the Plan B group, 20 pregnancies occurred in 1,183 women. The number of pregnancies expected in each group was calculated based on the timing of intercourse with regard to each woman's menstrual cycle. Among women receiving Plan B One-Step, 84% of expected pregnancies were prevented and among those women taking Plan B, 79% of expected pregnancies were prevented. The expected pregnancy rate of 8% (with no contraceptive use) was reduced to approximately 1% with Plan B One-Step.

Emergency contraceptives are not as effective as routine contraception since their failure rate, while low based on a single use, would accumulate over time with repeated use [see *INDICATIONS AND USAGE (1)*].

In the clinical study, bleeding disturbances were the most common adverse event reported after taking the levonorgestrel-containing regimens. More than half of the women had menses within two days of the expected time; however, 31% of women experienced change in their bleeding pattern during the study period; 4.5% of women had menses more than 7 days after the expected time.

## 16 HOW SUPPLIED/STORAGE AND HANDLING

The Plan B One-Step (levonorgestrel) tablet 1.5 mg is available in a PVC/aluminum foil blister package. The tablet is almost white, round, and marked G00 on one side.

NDC 51285-088-88 (1 tablet unit of use package)

Store Plan B One-Step at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

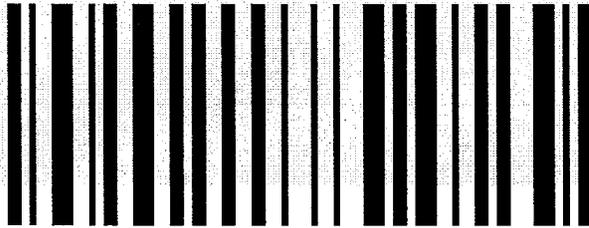
## 17 PATIENT COUNSELING INFORMATION

### 17.1 Information for Patients

- Take Plan B One-Step as soon as possible and not more than 72 hours after unprotected intercourse or a known or suspected contraceptive failure.
- If you vomit within two hours of taking the tablet, immediately contact your healthcare provider to discuss whether to take another tablet.
- Seek medical attention if you experience severe lower abdominal pain 3 to 5 weeks after taking Plan B One-Step, in order to be evaluated for an ectopic pregnancy.
- After taking Plan B One-Step, consider the possibility of pregnancy if your period is delayed more than one week beyond the date you expected your period.
- Do not use Plan B One-Step as routine contraception.
- Plan B One-Step is not effective in terminating an existing pregnancy.
- Plan B One-Step does not protect against HIV-infection (AIDS) and other sexually transmitted diseases/infections.
- For women younger than age 17 years, Plan B One-Step is available only by prescription.

Mfg. by Gedeon Richter, Ltd., Budapest, Hungary  
for Duramed Pharmaceuticals, Inc.  
Subsidiary of Barr Pharmaceuticals, Inc.  
Pomona, New York 10970  
Phone: 1-800-330-1271  
Website: [www.PlanBOneStep.com](http://www.PlanBOneStep.com)

Revised: July 2009  
11001459



*ceptive.*  
*d happens.*  
One-Step,

PlanB<sup>®</sup>  
One-Step  
levonorgestrel tablet

**Emergency  
Contraceptive**

From the makers of Plan B<sup>®</sup>, Duramed Pharmaceuticals, Inc., a subsidiary of Barr Pharmaceuticals, Inc.

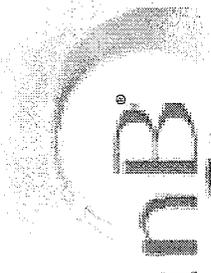
## What is Plan B® One-Step?

Plan B® One-Step is emergency contraception that helps prevent pregnancy after birth control failure or unprotected sex. It is a **backup** method of preventing pregnancy and is not to be used routinely.

Plan B® One-Step can reduce your chance of pregnancy after unprotected sex (if your regular birth control was used incorrectly or fails, or if you have had sex without birth control). For example, if you were using a condom and it broke or slipped, if you did not use your regular birth control as you should have, or if you did not use any birth control, Plan B® One-Step may work for you.

## **What Plan B® One-Step is not.**

Plan B® One-Step will not work if you are already pregnant and will not affect an existing pregnancy. Plan B® One-Step should not be used as regular birth control. It is important to have another reliable source of birth control that is right for you. Plan B® One-Step will not protect you from HIV infection (the virus that causes AIDS) and other sexually transmitted diseases.



**Plan B®**  
**One-Step**  
levonorgestrel) tablet, 1.5 mg

## **When is the appropriate time to use Plan B® One-Step?**

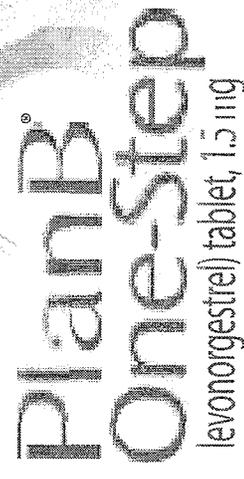
You can use Plan B® One-Step **after** you have had unprotected sex in the last 72 hours (3 days), and you do not want to become pregnant.

Plan B® One-Step can be used as a backup or emergency method to regular birth control if, for example,

- Your regular birth control method was used incorrectly or failed (your partner's condom broke or slipped)
- You made a mistake with your regular method
- You did not use any birth control method

## When is it not appropriate to use Plan B® One-Step?

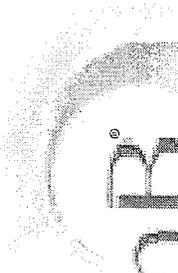
- Plan B® One-Step should not be used as a regular birth control method. It does not work as well as most other forms of birth control when they are used consistently and correctly. Plan B® One-Step is a backup or emergency method of contraception.
- Plan B® One-Step should not be used if you are already pregnant because it will not work.
- Plan B® One-Step should not be used if you are allergic to levonorgestrel or any other ingredients in Plan B® One-Step.

  
levonorgestrel) tablet, 1.5 mg

- Plan B® One-Step does not protect against HIV (the virus that causes AIDS) or other sexually transmitted diseases (STDs). The best ways to protect yourself against getting HIV or other STDs are to use a latex condom correctly with every sexual act or not to have sex at all.

## How does Plan B® One-Step work?

Plan B® One-Step is one pill with levonorgestrel, a hormone that has been used in many birth control pills for over 35 years. Plan B® One-Step contains a higher dose of levonorgestrel than birth control pills, but works in a similar way to prevent pregnancy. It works mainly by stopping the release of an egg from the ovary. It is possible that Plan B® One-Step may also work by preventing fertilization of an egg (the uniting of sperm with the egg) or by preventing attachment (implantation) to the uterus (womb).

The logo for Plan B One-Step features a stylized white crescent moon above the brand name. The text 'Plan B' is in a large, bold, sans-serif font, with a registered trademark symbol (®) to the upper right of the 'B'. Below it, 'One-Step' is written in a smaller, similar font. Underneath the brand name, 'levonorgestrel) tablet, 1.5 mg' is printed in a very small, light-colored font.**Plan B®**  
**One-Step**  
levonorgestrel) tablet, 1.5 mg

## **How can I get the best results from Plan B® One-Step?**

You have only a few days to try to prevent pregnancy after unprotected sex. **The sooner you take Plan B® One-Step, the better it works.** Plan B® One-Step should be taken **as soon as possible within 72 hours (3 days)** after unprotected sex.

## **How effective is Plan B® One-Step?**

The sooner you take Plan B® One-Step, the better it will work. Take Plan B® One-Step as soon as possible after unprotected sex. If it is taken as soon as possible within 72 hours (3 days) after unprotected sex, it will significantly decrease the chance that you will get pregnant. Seven out of every 8 women who would have gotten pregnant will not become pregnant.

## **How will I know if Plan B® One-Step worked?**

Most women will have their next menstrual period at the expected time or within a week of the expected time. If your menstrual period is delayed beyond 1 week, you may be pregnant. You should get a pregnancy test and follow up with your healthcare professional.

**PlanB®**  
**One-Step**  
levonorgestrel) tablet, 1.5 mg

## **What if I am already pregnant and use Plan B® One-Step?**

There is no medical evidence that Plan B® One-Step would harm a developing baby. If you take Plan B® One-Step (accidentally) after you are already pregnant or it does not work and you become pregnant, it is not likely to cause any harm to you or your pregnancy. The pregnancy will continue. Plan B® One-Step will not work if you are already pregnant.

## **What should I do if my menstrual period is delayed beyond 1 week and I have severe lower stomach (abdominal) pain?**

If you have severe lower stomach (abdominal) pain about 3 to 5 weeks after taking Plan B<sup>®</sup> One-Step, you may have a pregnancy outside the uterus, which is called a tubal pregnancy. A tubal pregnancy requires immediate medical treatment, so you should see a healthcare professional right away.

**PlanB<sup>®</sup>**  
**One-Step**  
levonorgestrel) tablet, 1.5 mg

## **Can I use Plan B® One-Step for regular birth control?**

No. Plan B® One-Step should not be used for regular birth control. It is an emergency or backup method to be used if your regular birth control fails or is used incorrectly or if you have sex without birth control. You should protect yourself against STDs and pregnancy every time you have sex. If you have unprotected sex again after taking Plan B® One-Step, it will not help protect you from getting pregnant.

## **How often can I use Plan B® One-Step?**

Plan B® One-Step is meant for emergency protection only, and is not designed to be used frequently. If you find that you need to use emergency contraception often, talk to your healthcare professional and learn about methods of birth control and STD prevention that are right for you.

**PlanB®**  
**One-Step**  
levonorgestrel) tablet, 1.5 mg

## **Will I experience any side effects from Plan B® One-Step?**

When used as directed, Plan B® One-Step is safe for women. Some women will have mild, temporary side effects, such as menstrual changes, nausea, lower stomach (abdominal) pain, tiredness, headache, dizziness, breast pain and vomiting. These are similar to the side effects that some women have when taking regular birth control pills. Some women taking Plan B® One-Step will have menstrual changes such as spotting or bleeding before their next period. Some women may have a heavier or lighter next period, or a period that is early or late. **If your period is more than a week late, you should get a pregnancy test.**

## **What warnings should I know about when using Plan B® One-Step?**

Plan B® One-Step does not protect against the AIDS virus (HIV) or other sexually transmitted diseases (STDs).

**Plan B®**  
**One-Step**  
levonorgestrel) tablet, 1.5 mg

## **Do not use:**

- If you are already pregnant (because it will not work)
- If you are allergic to levonogestrel or any of the ingredients in Plan B® One-Step
- For regular birth control

## **When using this product, you may have:**

- Menstrual changes
- Nausea
- Lower stomach (abdominal) pain
- Tiredness
- Headache
- Dizziness
- Breast pain
- Vomiting

## **Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away at 1-800-222-1222.

## **What are the directions for using Plan B<sup>®</sup> One-Step?**

### **Women 17 years of age and older:**

- Take Plan B<sup>®</sup> One-Step as soon as possible within 72 hours (3 days) after unprotected sex.
- If you vomit within 2 hours of taking the medication, call a healthcare professional to find out if you should repeat the dose.

Prescription only for women younger than age 17. If you are younger than age 17, see a healthcare professional.

## **What should I do if I have questions about Plan B® One-Step?**

If you have questions or need more information about this product, call our toll-free number, 1-800-330-1271, visit our website at [www.PlanBOneStep.com](http://www.PlanBOneStep.com), or ask a healthcare professional.

## **Other information**

Tablet is enclosed in a blister seal. **Do not use if the blister seal is broken.**

Store at room temperature 20–25°C (68–77°F).

You may report side effects to FDA at 1-800-FDA-1088.

**Active ingredient:** levonorgestrel 1.5 mg

**Inactive ingredients:** colloidal silicon dioxide, potato starch, magnesium stearate, talc, corn starch, lactose monohydrate

### **Protect yourself in more ways than one!**

If you are sexually active, but you are not ready for a pregnancy, it is important to use regular pregnancy protection. There are many types of birth control. Whichever type you choose, it is important to use your regular birth control method as directed.

This ensures that you have effective protection against pregnancy every time you have sex.

**PlanB<sup>®</sup>**  
**One-Step**  
levonorgestrel) tablet, 1.5 mg

But things do not always go as planned. For example, if you were using a condom and it broke or slipped, or if you did not use your regular birth control as you should have, or if you did not use any birth control, Plan B® One-Step may work for you. Plan B® One-Step is an emergency contraceptive that helps prevent pregnancy after unprotected sex or when your birth control fails or is not used correctly.

Remember, Plan B® One-Step is only for emergency pregnancy prevention. There are many other products that work for regular birth control that are available by prescription or over-the-counter.

There is also another form of protection to think about when you have sex: protection against sexually transmitted diseases (STDs). Some common STDs are HIV/AIDS, chlamydia, genital herpes, gonorrhea, hepatitis, human papilloma virus (HPV), genital warts, syphilis, and trichomonas. Some of these STDs can be very serious and can lead to infertility (inability to have a baby), problems during pregnancy, chronic illness, and even death.

All sexually active women are at risk of catching STDs because they may not know that their partner has an STD (the partner

**himself may not know). If your partner uses a latex condom correctly each and every time you have sex with him, this will help reduce, but not eliminate, the chance that you will catch an STD.**

The logo for PlanB One-Step features a stylized white 'P' inside a grey circle. To the right of the circle, the text 'PlanB' is written in a large, bold, sans-serif font, with a registered trademark symbol (®) to its upper right. Below 'PlanB', the words 'One-Step' are written in a smaller, bold, sans-serif font. Underneath 'One-Step', the text 'levonorgestrel) tablet, 1.5 mg,' is written in a very small, regular font.

PlanB<sup>®</sup>  
One-Step  
levonorgestrel) tablet, 1.5 mg,

No other birth control methods will effectively protect you from STDs. The female condom may give you some STD protection, but it is not as effective as a male latex condom.

For more information on STDs, call the Centers for Disease Control and Prevention (CDC) AIDS/STD Hotline. The CDC phone numbers are 1-800-342-AIDS (2437) for English, 1-800-344-7432 for Spanish, or 1-800-243-7889 for hearing impaired, TDD.

Be sure to protect yourself against pregnancy and STDs by using some form of birth control plus a latex condom. Of course, not having sex is the most effective way to prevent pregnancy and stay free of STDs.

Plan B® One-Step is used to prevent pregnancy after unprotected sex.

**Plan B® One-Step should not be used for regular birth control, if you are already pregnant (because it will not work), or if you are allergic to levonorgestrel or any of the ingredients in Plan B® One-Step.**

**The sooner you take Plan B® One-Step, the better it will work.**

**PlanB®**  
**One-Step**  
levonorgestrel) tablet, 1.5 mg

**Plan B® One-Step does not protect against the AIDS virus (HIV) or other sexually transmitted diseases (STDs)**

Common side effects associated with the use of Plan B® One-Step include menstrual changes, nausea, lower stomach (abdominal) pain, tiredness, headache, dizziness, breast pain and vomiting.

1-800-330-1271

www.PlanBOneStep.com

**DURAMED**<sup>®</sup>

Mfg. by Gedeon Richter, Ltd., Budapest, Hungary  
for Duramed Pharmaceuticals, Inc.  
Subsidiary of Barr Pharmaceuticals, Inc.  
Pomona, New York 10970

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12001119

July 2009

Printed in USA

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One-Step**  
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