

HIGHLIGHTS OF PRESCRIBING INFORMATION

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

Plan B (levonorgestrel) tablets, 0.75mg, for oral use

Initial U.S. Approval: 1982

INDICATIONS AND USAGE

Plan B is a progestin-only emergency contraceptive, indicated for prevention of pregnancy following unprotected intercourse or a known or suspected contraceptive failure. Plan B 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 is not intended for routine use as a contraceptive. (1)

DOSAGE AND ADMINISTRATION

The first tablet is taken orally as soon as possible within 72 hours after unprotected intercourse. The second tablet should be taken 12 hours after the first dose. Efficacy is better if Plan B is taken as soon as possible after unprotected intercourse. (2)

DOSAGE FORMS AND STRENGTHS

A total of two 0.75 mg tablets taken 12 hours apart as a single course of treatment (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 should be evaluated for ectopic pregnancy. (5.1)

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

ADVERSE REACTIONS

The most common adverse reactions ($\geq 10\%$) in the clinical trial included menstrual changes (26%), nausea (23%), abdominal pain (18%), fatigue (17%), headache (17%), dizziness (11%), and breast tenderness (11%). (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.

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 is not intended for use in premenarcheal (8.4) or postmenopausal females (8.5).
- Clinical trials demonstrated a higher pregnancy rate in the Chinese population. (8.6)

See 17 for PATIENT COUNSELING INFORMATION

Revised: 7/2009

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Plan B® 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 first tablet should be taken as soon as possible within 72 hours of intercourse. The second tablet should be taken 12 hours later.

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

2 DOSAGE AND ADMINISTRATION

Take one tablet of Plan B 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. The second tablet should be taken 12 hours after the first dose. Plan B can be used at any time during the menstrual cycle.

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

3 DOSAGE FORMS AND STRENGTHS

Each Plan B tablet is supplied as a white, round tablet containing 0.75 mg of levonorgestrel and is marked with INOR on one side.

4 CONTRAINDICATIONS

Plan B 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. 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.

5.2 Existing Pregnancy

Plan B 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. 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 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. 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.

5.6 Fertility Following Discontinuation

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

6 ADVERSE REACTIONS

6.1 Clinical Trial 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.

A double-blind, controlled clinical trial in 1,955 evaluable women compared the efficacy and safety of Plan B (one 0.75 mg tablet of levonorgestrel taken within 72 hours of unprotected intercourse, and one tablet taken 12 hours later) to the Yuzpe regimen (two tablets each containing 0.25 mg levonorgestrel and 0.05 mg ethinyl estradiol, taken within 72 hours of intercourse, and two tablets taken 12 hours later).

The most common adverse events (>10%) in the clinical trial for women receiving Plan B included menstrual changes (26%), nausea (23%), abdominal pain (18%), fatigue (17%), headache (17%), dizziness (11%), and breast tenderness (11%). Table 1 lists those adverse events that were reported in $\geq 5\%$ of Plan B users.

Table 1: Adverse Events in $\geq 5\%$ of Women, by % Frequency

	Plan B Levonorgestrel N=977 (%)
Nausea	23.1
Abdominal Pain	17.6
Fatigue	16.9
Headache	16.8
Heavier Menstrual Bleeding	13.8
Lighter Menstrual Bleeding	12.5
Dizziness	11.2
Breast Tenderness	10.7
Vomiting	5.6
Diarrhea	5.0

6.2 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of Plan B. 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 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). 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.

8.8 Renal Impairment

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

9 DRUG ABUSE AND DEPENDENCE

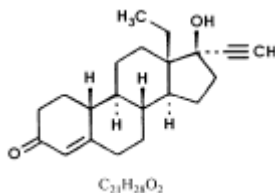
Levonorgestrel is not a controlled substance. There is no information about dependence associated with the use of Plan B.

10 OVERDOSAGE

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

11 DESCRIPTION

Each Plan B tablet contains 0.75 mg of a single active steroid ingredient, levonorgestrel [18,19-Dinorpregn-4-en-20-yn-3-one-13-ethyl-17-hydroxy-, (17 α)-(-)-], a totally synthetic progestogen. The inactive ingredients present are colloidal silicon dioxide, potato starch, gelatin, magnesium stearate, talc, corn starch, and lactose monohydrate. 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 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

No specific investigation of the absolute bioavailability of Plan B in humans has been conducted. However, literature indicates that levonorgestrel is rapidly and completely absorbed after oral administration (bioavailability about 100%) and is not subject to first pass metabolism.

After a single dose of Plan B (0.75 mg) administered to 16 women under fasting conditions, the mean maximum serum concentration of levonorgestrel was 14.1 ng/mL at an average of 1.6 hours. See Table 2.

Table 2: Pharmacokinetic Parameter Values Following Single Dose Administration of Plan B (Levonorgestrel) Tablets 0.75 mg to Healthy Female Volunteers under Fasting Conditions

	Mean (\pm SD)					
	C _{max} (ng/mL)	T _{max} (h)	CL (L/h)	V _d (L)	t _{1/2} (h)	AUC _{inf} (ng·hr/mL)
Levonorgestrel	14.1 (7.7)	1.6 (0.7)	7.7 (2.7)	260.0	24.4 (5.3)	123.1 (50.1)

C_{max} = maximum concentration
T_{max} = time to maximum concentration
CL = clearance
V_d = volume of distribution
t_{1/2} = elimination half life
AUC_{inf} = area under the drug concentration curve from time 0 to infinity

Effect of Food: The effect of food on the rate and the extent of levonorgestrel absorption following single oral administration of Plan B 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 β -OH position to form sulfate conjugates and, to a lesser extent, glucuronide conjugates in plasma. Significant amounts of conjugated and unconjugated 3 α , 5 β -tetrahydrolevonorgestrel are also present in plasma, along with much smaller amounts of 3 α , 5 α -tetrahydrolevonorgestrel and 16 β 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 on pharmacokinetics of Plan B. However, clinical trials demonstrated a higher pregnancy rate in Chinese women with both Plan B and the Yuzpe regimen (another form of emergency contraception). 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.

Renal Impairment: No formal studies were conducted to evaluate the effect of renal disease on the disposition of Plan B.

Drug-Drug Interactions

No formal drug-drug interaction studies were conducted with Plan B [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 μ 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 μ 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, multinational controlled clinical trial in 1,955 evaluable women (mean age 27) compared the efficacy and safety of Plan B (one 0.75 mg tablet of levonorgestrel taken within 72 hours of unprotected intercourse, and one tablet taken 12 hours later) to the Yuzpe regimen (two tablets each containing 0.25 mg levonorgestrel and 0.05 mg ethinyl estradiol, taken within 72 hours of intercourse, and two additional tablets taken 12 hours later). After a single act of intercourse occurring anytime during the menstrual cycle, the expected pregnancy rate of 8% (with no contraceptive use) was reduced to approximately 1% with Plan B.

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

At the time of expected menses, approximately 74% of women using Plan B had vaginal bleeding similar to their normal menses, 14% bled more than usual, and 12% bled less than usual. The majority of women (87%) had their next menstrual period at the expected time or within + 7 days, while 13% had a delay of more than 7 days beyond the anticipated onset of menses.

16 HOW SUPPLIED/STORAGE AND HANDLING

Plan B (levonorgestrel) tablets, 0.75 mg, are available for a single course of treatment in PVC/aluminum foil blister packages of two tablets each. The tablet is white, round and marked INOR on one side.

Available as: Unit-of-use NDC 51285-769-93

Store Plan B tablets at controlled room temperature, 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [see USP].

17 PATIENT COUNSELING INFORMATION

17.1 Information for Patients

- Take Plan B 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 either 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, in order to be evaluated for an ectopic pregnancy.
- After taking Plan B, 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 as routine contraception.
- Plan B is not effective in terminating an existing pregnancy.
- Plan B does not protect against HIV-infection (AIDS) and other sexually transmitted diseases/infections.
- For women younger than age 17 years, Plan B 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.go2planb.com

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*Plan B[®]
Emergency Contraceptive.
Because the unexpected happens.*

*Important Information About Plan B[®],
Birth Control & Sexually Transmitted Diseases*

For additional information intended for
healthcare professionals, please see
enclosed Product Information for Plan B[®].



Plan B[®]
(LEVONORGESTREL)
tablets 0.020 mg

**Emergency
Contraceptive**

From the makers of Plan B[®], Duramed Pharmaceuticals, Inc., a subsidiary of Barr Pharmaceuticals, Inc.

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What is Plan B®?

Plan B® 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® 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® may work for you.

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What Plan B® is not.

Plan B® will not work if you are already pregnant and will not affect an existing pregnancy. Plan B® 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® will not protect you from HIV infection (the virus that causes AIDS) and other sexually transmitted diseases.



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When is the appropriate time to use Plan B®?

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

Plan B® 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

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When is it not appropriate to use Plan B®?

- Plan B® 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® is a backup or emergency method of contraception.
- Plan B® should not be used if you are already pregnant because it will not work.
- Plan B® should not be used if you are allergic to levonorgestrel or any other ingredients in Plan B®.



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- Plan B® 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.

**This label may not be the latest approved by FDA.
For current labeling information, please visit <https://www.fda.gov/drugs>**

How does Plan B® work?

Plan B® is two pills with levonorgestrel, a hormone that has been used in many birth control pills for over 35 years. Plan B® 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® 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).



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How can I get the best results from Plan B®?

You have only a few days to try to prevent pregnancy after unprotected sex. **The sooner you take Plan B®, the better it works.** Take the first Plan B® tablet **as soon as possible within 72 hours (3 days)** after unprotected sex. Take the second tablet **12 hours** later.

How effective is Plan B®?

The sooner you take Plan B®, the better it will work. Take Plan B® 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.

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How will I know if Plan B[®] 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.



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What if I am already pregnant and use Plan B®?

There is no medical evidence that Plan B® would harm a developing baby. If you take Plan B® (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® will not work if you are already pregnant.

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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®, 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.



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Can I use Plan B® for regular birth control?

No. Plan B® 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®, it will not help protect you from getting pregnant.

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For current labeling information, please visit <https://www.fda.gov/drugs>**

How often can I use Plan B®?

Plan B® 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.



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Will I experience any side effects from Plan B®?

When used as directed, Plan B® 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® 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.**

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What warnings should I know about when using Plan B®?

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



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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®
- For regular birth control

When using this product, you may have:

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

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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®?

Women 17 years of age and older:

- Take the first Plan B® tablet as soon as possible within 72 hours (3 days) after unprotected sex.
- Take the second tablet 12 hours after you take the first tablet.
- If you vomit within 2 hours of taking either dose of medication, call a healthcare professional to find out if you should repeat that dose.

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

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What should I do if I have questions about Plan B®?

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.go2PlanB.com, or ask a healthcare professional.

Other information

Tablets are 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.

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Active ingredient: levonorgestrel 0.75 mg in each tablet

Inactive ingredients: colloidal silicon dioxide, potato starch, gelatin, 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.



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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® may work for you. Plan B® 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® 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.

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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.**



**This label may not be the latest approved by FDA.
For current labeling information, please visit <https://www.fda.gov/dru>**

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.

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For current labeling information, please visit <https://www.fda.gov/drugs>**

Plan B[®] is used to prevent pregnancy after unprotected sex.

Plan B[®] 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[®].

The sooner you take Plan B[®], the better it will work.



**This label may not be the latest approved by FDA.
For current labeling information, please visit <https://www.fda.gov/drugs>**

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

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

This label may not be the latest approved by FDA.
For current labeling information, please visit <https://www.fda.gov/drugs>

1-800-330-1271

www.go2planB.com



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DURAMED PHARMACEUTICALS, INC.

CARESM **(CONVENIENT ACCESS, RESPONSIBLE EDUCATION) PROGRAM** **THE MARKETING, EDUCATION, DISTRIBUTION,** **AND MONITORING PROGRAM FOR** **PLAN B[®]**

Introduction

The CARESM (Convenient Access, Responsible Education) Program was carefully constructed to help ensure that Plan B[®] will be used responsibly and appropriately.

Plan B[®] is an over-the-counter (OTC) product for women age 17 or older, with a prescription-only requirement for women younger than age 17. The sales and marketing plan for Plan B[®] has been designed to limit the availability of this product, to the extent practical, to pharmacies and clinics, and to educate healthcare professionals and consumers within the target age groups regarding the responsible use of Plan B[®]. The need to take Plan B[®] in as timely a manner as possible dictates that any responsible marketing program not only address healthcare professionals but also include extensive consumer education. Thus, the CARESM program contains elements that include an appropriate consumer education component. In addition, the sponsor will work closely with retail pharmacies and drug wholesalers to ensure that they will carry Plan B[®], and that they will understand and follow the prescription age requirement for the dispensing of the product to women younger than age 17.

The CARESM program is intended to address issues affecting access to Plan B[®] by providing sources of accurate and responsible information to both healthcare providers and consumers. It is also designed to provide a framework for pharmacies to ensure availability of Plan B[®] as an OTC product when sought by knowledgeable consumers who are 17 years or older. Women younger than age 17 will require a prescription from their healthcare provider in order to obtain Plan B[®]. The CARESM program is not



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intended to impact or change those who can lawfully prescribe or dispense Plan B[®] under prevailing state laws.

Four core elements of CARESM contribute to the achievement of program objectives.

- Labeling/Packaging/Informational toll free number (to provide essential information to consumers in an accessible, easy to understand format. The Plan B[®] packaging is designed to meet both prescription and OTC requirements.)
- Education (to provide information intended to educate physicians, pharmacists, pharmacy staff, nurse practitioners, and patients. Educational initiatives will focus on clearly instructing all audiences on the new lower age requirement that women younger than age 17 obtain a prescription for Plan B[®].)
- Distribution (to ensure that Plan B[®] will be available only to licensed drug wholesalers, retail operations with pharmacy services and clinics with licensed healthcare practitioners, and to successfully facilitate the Plan B[®] prescription-only age requirement. These settings will also provide easy access by the consumer to a pharmacist or other healthcare professional should questions arise.)
- Monitoring (to evaluate the effectiveness of the program by determining if the age restriction is understood by all audiences and is properly being adhered to.)

I. Labeling/Packaging

The Plan B[®] labeling was developed to provide clear and comprehensive communication of the key messages outlined above, and to make known additional sources of information. The Plan B[®] packaging is designed to meet all requirements of both a prescription and over-the-counter product. The Plan B[®] packaging allows pharmacies to



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appropriately dispense Plan B[®] as either a prescription or OTC product. The package also provides educational information to the consumer in a patient friendly format.

Elements of the package are as follows:

- The back of the carton includes the Drug Facts as well as a space for the pharmacy to place the required prescription labeling;
- The statement, “Rx only for women younger than age 17” appears on the Principal Display Panel and “prescription only for women younger than age 17. If you are younger than age 17, see a healthcare professional” appears on the Drug Facts panel of the carton;
- The inner portion of the carton houses the Plan B[®] tablet and clearly states the directions for when to take Plan B[®];
- The Plan B[®] Package Insert and an educational booklet designed for the consumer (Consumer Information Leaflet) will be housed inside the carton;
- The toll-free number for the Plan B[®] 24-hour Information Line and the Plan B[®] web address are clearly displayed in the Drug Facts panel of the package should the consumer have additional questions on Plan B[®].

II. Education

The CARESM Program provides for an intensively educational approach to the introduction of Plan B[®] as an OTC product to those age 17 years or older. Educational programs will focus on both healthcare professionals as well as consumers. The



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consumer advertising is designed to stimulate discussions with healthcare providers. The program will assist healthcare providers in developing an adequate knowledge base so that they can provide responsible and accurate counseling to patients.

Efforts directed to raising consumer awareness of the product and its appropriate use will follow appropriate professional education programs. The educational materials will address not only Plan B[®] but will encourage healthcare professionals to urge users to adopt routine forms of contraception and avoid reliance on Plan B[®] as their primary form of birth control.

A. Educational Program to Healthcare Professionals.

Plan B[®] will be introduced and explained to healthcare professionals to raise awareness and knowledge levels as to this product for emergency contraception. This program is intended to ensure that healthcare professionals are prepared to support their patient populations.

Specifically, the new lower prescription age requirement will be emphasized to healthcare professionals to ensure that they are knowledgeable of the prescription requirement for women younger than age 17 and that they understand how to appropriately dispense the Plan B[®] package in both prescription and OTC scenarios.

Programs will include continuing education by certified professionals and educational materials (including websites and toll free numbers) that can be accessed easily and at any time. The sponsor will make available to the state boards of pharmacy Continuing Education programs for pharmacists. The sponsor's sales



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representatives¹ will communicate the prescription requirement for women younger than age 17 as well as the OTC availability of Plan B[®] for those 17 years of age or older.

B. Educational Campaign to Consumers

1. The campaign is designed to convey critical awareness and educational messages as well as information about product availability, the time sensitivity of use, and the age requirements to obtain Plan B[®] as a prescription or OTC product. The intent will be to make consumers aware of the availability of emergency contraception, its appropriate use and the need to use it as soon as possible. Women younger than age 17 will be encouraged to contact their healthcare professional to learn about emergency contraception, routine forms of birth control, and sexually transmitted infection (STI)/human immunodeficiency virus (HIV).
2. The direct to consumer campaign will be designed to target those ages 17 to 44.
 - i) The language and visuals used will be appropriate and of interest to this targeted age group. As appropriate, new promotional materials will be provided to FDA for comment. Promotional materials will be submitted to the Division of Drug Marketing, Advertising, and Communications via Form FDA 2253.
 - ii) Media placements that target audiences younger than age 17 will not be used.

¹ The sponsor's sales force for female healthcare products, currently consisting of approximately 230 sales representatives, visit the offices of approximately 30,000 physicians, mostly Obstetricians and Gynecologists.



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III. Distribution

The sponsor believes that in the interest of responsible usage (and in recognition of the circumstances of the need for emergency contraception), Plan B[®] should be available in those retail pharmacy outlets that typically sell a broad range of OTC medications and that have pharmacy services staffed with pharmacists (or, in the case of clinics, other healthcare professionals) during normal business hours to answer questions. Since Plan B[®] will have a prescription only requirement for women younger than age 17, Duramed Pharmaceuticals and the third party distributors, wholesaler distribution and chain drug companies, will only be allowed to distribute Plan B[®] to licensed pharmacies or other licensed healthcare clinics, as it would be unlawful to distribute a prescription product to any business that does not have a valid pharmacy license and/or physician license. Since Plan B[®] has both Rx and OTC labeling, it will be treated as any other Rx product for distribution purposes; specifically, it would only be distributed to licensed pharmacies or healthcare clinics. Therefore, Plan B[®] will not be available at gas stations or convenience stores. Additionally, since Plan B[®] has both Rx and OTC labeling, the pharmacies will keep the product behind the counter and control it as an Rx product. The pharmacy and clinic settings will also allow pharmacists and other healthcare providers to properly restrict OTC access to those age 17 years or older.

IV. Monitoring

The sponsor intends to monitor trends in the use of emergency contraception to evaluate the effectiveness of the CARESM program and will make adjustments as appropriate. Monitoring will be accomplished in several ways, with information gathered from both healthcare professionals and consumers.

Monitoring actual use of Plan B[®] is complex due to the difficulties inherent in identifying



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those who have purchased the product and in gathering useful, generalizable information. Consequently, the monitoring component will rely on a variety of sources intended to provide trend data, observational data, and signals of program effectiveness and potential problems. Monitoring components may include the following:

1. A market research survey or surveys of a subset of healthcare professionals (e.g. OB/GYN, family practice, pharmacists, nurses, family planning and health clinic personnel) to determine:
 - Whether the prescription requirement for women younger than age 17 is understood and is being adhered to at the point of purchase
 - Attitudes toward and experience with patients' usage of Plan B[®]
 - Trends among emergency contraception users within their patient population (especially source of awareness, repeat use, use instead of more effective forms of contraception, incidence of STIs, etc.)
 - Nature of interactions with Plan B[®] users (Does the contact with the healthcare professional occur prior to product usage? after usage? Are the women in search of contraceptive counseling? What types of side effects are being seen in use?)
 - Areas where additional information is needed in the marketplace, as identified by the questions raised by the users

2. Gathering data from actual users of Plan B[®] is difficult because the number of users will be relatively small and because the decision to use emergency contraception is a private and emotional one. Women choosing to use the product are expected to wish to remain anonymous and are entitled to maintain their privacy. Nevertheless, the sponsor may work with a variety of sources in an



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effort to obtain and analyze consumer data in accordance with HIPAA regulations to assess the effectiveness of the CARESM program elements.

3. Monitoring compliance of the Plan B[®] prescription age requirement can be somewhat complex because there will be no documented information on the purchasers of Plan B[®] who were old enough to obtain it as an OTC product. The sponsor intends to monitor the level of comprehension of the prescription age requirement particularly at the pharmacy level, where the age of consumers must be assessed at the point of purchase. The following program will provide accurate information directly related to accessing compliance:

- **Point of Purchase Monitoring Program:**

The sponsor will continue to conduct a “Point-of-Purchase Monitoring Program”, which intends to track how Plan B[®] is being sold at the time of purchase. Due to the challenges of obtaining specific purchase data on an OTC product and respecting consumer privacy, this program will include anonymous shoppers who will be directed to visit locations where Plan B[®] is available and purchase the product. These transactions will be documented and analyzed to determine the level of comprehension of the Plan B[®] prescription age requirement and how it is handled at the point of purchase. The shoppers in this program will be 15 to 16 years old. Parental consent will be obtained for the shoppers as they will be under the age of 18 years. Locations for this program will be selected based on areas where Plan B[®] use is high, and will be in different regions of the US to provide a national representation of the findings. These findings would provide concrete information on how the prescription age requirement for Plan B[®] is being addressed at the pharmacy and if it is properly being followed. The Sponsor will use these findings to identify areas where more education on



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the prescription age restriction is needed and will focus their efforts on improving the level of understanding among pharmacists and the pharmacy staff. Findings from the study will be communicated to the pharmacy, and the corporate office, if appropriate, since education and retraining will be the first course of remedial action. In the case of repeat violators, the violator's State Board of Pharmacy will be notified. The Point-of-Purchase Monitoring Program will be conducted annually.

V. Reporting

The sponsor will continue to provide FDA a monitoring report with the available results from the above monitoring activities, including the point of purchase monitoring, on an annual basis, with submission of the report within 60 calendar days after the interval date. Any change in reporting period will be requested by the sponsor and agreed to by FDA.

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