

LABELING

The Plan B® product labeling in this section consists of the prototype label used in the Label Comprehension Study (see Tab 5 for a discussion of the Label Comprehension Study), the prototype label used in the Actual Use Study (see Tab 2 for a discussion of the Actual Use Study) and the company's proposed labeling for the OTC commercial product. The proposed labeling for the OTC commercial product consists of carton labeling and two inserts, a patient insert further discussing the appropriate use of Plan B®, and an insert discussing alternate methods of birth control.

There were three main changes between the Actual Use Study prototype label and the proposed commercial labeling, which are listed below:

1. The warning on undiagnosed vaginal bleeding was moved from the contraindications (Panel 2) to the warnings (Panel 4).
2. The percentages listed for the incidence of side effects was removed (Panel 4).
3. The two package inserts were added.

Carton Labeling for Actual Use Study Carton

Panel 4 →

Panel 2 →

WHAT IS PLAN B?
Plan B is a backup contraceptive. It can prevent pregnancy after unprotected sex (if a contraceptive fails or if no birth control method was used). Plan B should not be used in place of regular contraception. It does not work as well as most other contraceptives used correctly.

- Plan B does not prevent HIV (the virus causing AIDS) or other sexually transmitted diseases.

WHO SHOULD NOT USE PLAN B?

- Pregnant women (Plan B cannot cause an abortion.)
- Women who are allergic to any ingredient in Plan B.
- Women who have unusual vaginal bleeding.

WHAT IF I AM ALREADY PREGNANT AND USE PLAN B?
If you are already pregnant Plan B is unlikely to harm the fetus.

HOW WELL DOES PLAN B WORK?
Plan B lowers the risk of pregnancy by 89% after one act of unprotected sex (from about 6%, on average, down to about 1%). If used within 72 hours (3 days).

Plan B works better the sooner you use it after unprotected sex.

1

Take the first tablet as soon as possible after unprotected sex.

2

Take the second tablet 12 hours after you take the first tablet.

Side Effects
Possible side effects may include:

- Nausea (31% of users)
- Stomach pain (18%)
- Fatigue (17%)
- Headache (17%)
- Dizziness (10%)
- Breast pain (10%)
- Vomiting (6%)
- Diarrhea (6%)

Talk to a doctor if side effects are severe or last more than 48 hours.

See a doctor right away if you have severe stomach pain, since this can be a warning sign of a tubal (ectopic) pregnancy - a serious medical problem.

After taking Plan B you may have spotting or your menstrual period might be heavier (14% of users) or lighter (13%). Your next period should come at the normal time, or a few days early or late. If your period is more than one week late, you may be pregnant.

Drug Facts
Active ingredient (in each tablet) *Purpose*
Levonorgestrel 0.75 mg Emergency Contraception
Use Reduces chance of pregnancy after unprotected sex (if a contraceptive failed or if you did not use birth control)

Warnings
Do not use:
- if you are already pregnant (because it will not work)
- if you have unusual vaginal bleeding or other symptoms of pregnancy (because you may be pregnant)

Plan B is not recommended for regular contraception. Plan B does not protect against HIV (the virus that causes AIDS) or any other sexually transmitted diseases.

Other information you may want to know:

- Keep out of the reach of children.
- Keep out of the reach of children.
- Keep out of the reach of children.

Directions
- Take the second tablet 12 hours after you take the first tablet.
- If you are already pregnant, you may have:
 • spotting • headache
 • dizziness • breast pain

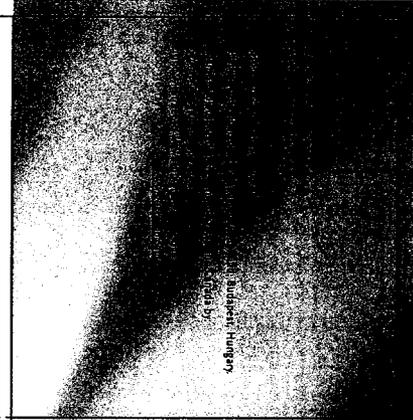
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Lot# W110004 **NDC#** 64816-002

Expiration Date 11/02 **Date of Manufacture** 11/02

PRO BLUE **PMS 289** **MATCH BLUE**



Plan B[®]
Emergency Contraception

White, oval-shaped tablets
0.75 mg each

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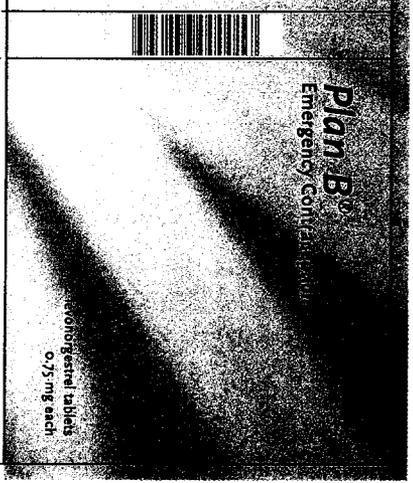
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PACKAGE INSERT - Appropriate Use of Plan B

What you should know about Plan B®

Plan B® is a backup method of birth control.

Plan B® is *emergency contraception*, a backup method of birth control. Plan B® can reduce your risk of pregnancy if you have unprotected sex (if your regular birth control method fails or if you have sex without birth control).

Plan B® contains a concentrated dose of *levonorgestrel*, a synthetic hormone used in birth control pills for over 35 years.

Because Plan B® prevents pregnancy before it begins, it is not the same as abortion.

You can use Plan B® if you had unprotected sex one or more times in the last three days (72 hours), and you don't want to become pregnant.

Plan B® is not as effective as using a regular birth control method correctly and consistently. It can be used as a backup method if:

- Your regular birth control failed (your partner's condom broke or slipped)
- You made a mistake with your regular method (you missed several birth control pills)
- You did not use any birth control method

Plan B® works better the sooner you use it.

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

Plan B® can reduce the risk of pregnancy to about 1 percent, if you use it within the first three days of a single act of unprotected sex. Your risk of pregnancy ranges from 0 to 35 percent, depending on the day of your menstrual cycle.

Plan B® works like other birth control pills.

Plan B® can prevent pregnancy by stopping the release of an egg from the ovary (*ovulation*), or it may prevent the union of sperm and egg (*fertilization*). You are at most risk of pregnancy just before ovulation and on the day of ovulation.

PACKAGE INSERT - Appropriate Use of Plan B (2)

If fertilization does occur, Plan B[®] may prevent a fertilized egg from attaching to the womb (*implantation*). Plan B[®] will not work after implantation of a fertilized egg.

Plan B[®] is not the same as the early abortion pill, Mifeprex[®] (RU486). Plan B[®] cannot disrupt an established pregnancy.

Some women experience short-term side effects?

Plan B[®] has no serious or lasting medical side effects. Some women will experience non-serious side effects, such as nausea, stomach pain, headache, dizziness, or breast tenderness. These are similar to the side effects of regular birth control pills. Some women 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.

Plan B will not harm an established pregnancy?

Plan B[®] should not have any effect on an established pregnancy.. If you take it accidentally after you are already pregnant, or if it does not work, it is not likely to cause any harm to you or your pregnancy. Studies of women who took birth control pills by mistake after they were already pregnant showed no increased risk of birth defects.

Warnings

If you become pregnant after using Plan B[®], and you have severe stomach pain, contact a doctor immediately. This may be a sign of an ectopic pregnancy (a pregnancy growing in your fallopian tube).

Keep this and all drugs out of the reach of children. In case of accidental ingestion, call a Poison Control Center, emergency medical facility, or a doctor immediately.

Each Plan B[®] package is sealed in plastic wrap. If the wrap is missing or torn, return the package to your pharmacy.

Questions or Comments

Call 1-800-330-1271 or visit www.go2planb.com

Package Insert - Alternate Methods of Birth Control

Choosing a Regular Method of Birth Control

Plan B® is a safe and effective emergency contraceptive for use when you need a backup method of birth control.

Plan B® is not a substitute for regular contraception. Using a regular contraceptive correctly and consistently would be more effective and may be less expensive. Plan B® does not protect you against sexually transmitted infections, including HIV/AIDS.

If you are sexually active but you are not using a regular birth control method, or if you are having trouble using your method, you should talk with a healthcare professional. Women who are sexually active and use no birth control method for a year have an 85% risk of becoming pregnant.

Listed below are birth control choices that you may want to discuss with your healthcare provider. In some cases, Plan B® may be a good backup for the method you choose.

Abstinence

Sexual abstinence is the most effective way to avoid both unintended pregnancy and sexually transmitted infections, including HIV/AIDS. Sexual abstinence requires commitment and self-control on the part of both partners in a relationship. For women practicing abstinence, Plan B® can be a useful back-up method, if unplanned sex does occur.

Birth Control Pill

Most birth control pills contain *progestin* and *estrogen*. These active ingredients are synthetic versions of naturally occurring female hormones. *Progestin*-only pills are available for women who should not take estrogen because of cardiovascular or other risk factors. All birth control pills currently require a prescription. Birth control pills are highly effective if they are used correctly and consistently. Because women sometimes forget to take their pills, the typical pregnancy rate in the first year of use is about 8%. Advantages of the pill include more regular periods, less menstrual bleeding, decreased menstrual cramps, and a reduction in the risk of endometrial and ovarian cancer. Side effects may include nausea, breast tenderness, and headaches, but these symptoms often decrease after the first few months of pill use. Birth control pills provide no protection against sexually transmitted infections or HIV/AIDS. Plan B® can be used as a backup contraceptive if you miss two or more pills in a row or if you start a new cycle of pills late. You can start taking your pills again as soon as you finish taking Plan B®.

Condom

Many different types of condoms for men are available in pharmacies without a prescription. Condoms can prevent pregnancy and can also reduce the risk of getting HIV/AIDS or other sexually transmitted infections. To be most effective, condoms must be used correctly and consistently. Condoms break or slip 3% to 5% of the time. As a result of condom accidents and inconsistent use, the typical risk of pregnancy is about 15% in the first year of use. A polyurethane female condom, worn inside the vagina, is also available without a prescription. The female condom can prevent both pregnancy and sexually transmitted infections, including HIV/AIDS. The risk of pregnancy is about 21% in the first year of typical use. Couples depending on male or female condoms for birth control may find it useful to keep Plan B® in the nightstand in case of a condom accident or if unprotected sex occurs.

Diaphragm, Cervical Cap and Sponge (Female Barrier Methods)

Female barrier methods prevent pregnancy by stopping sperm from reaching the uterus. The diaphragm and cap are used with a spermicide; the sponge contains a spermicide. (See

PACKAGE INSERT - Alternate Methods of Birth Control (2)

"Spermicides" below). These methods do not require a prescription. Plan B® can be a useful backup method when a diaphragm or cervical cap moves out of place during sex, or if unprotected sex occurs.

Implant (Contraceptive Implant)

New contraceptive implants, lasting for two or three years, are available in Europe and should be available soon in the United States. Implants allow the steady release of low doses of *progestin*, a synthetic version of a naturally occurring female hormone. Implants are highly effective and convenient for women who want long-term contraception. Pregnancy rates are less than 0.5% in the first year of typical use. Like other *progestin*-only methods, implants can cause irregular menstrual bleeding, including spotting and less frequent periods. Implants must be inserted under the skin and surgically removed by a healthcare professional.

Injectable Contraceptive

Injectable contraceptives (birth control shots) are highly effective and more convenient for some women than daily pills. Only 3% of users typically get pregnant in the first year of use. The shots generally work in the same way as birth control pills. There are two types available in the United States. Both require a prescription. Plan B® can be used as a backup if you are late getting your contraceptive injection.

Intrauterine Device (IUD)

IUDs are contraceptive devices that are inserted into the uterus. They can work for ten years or more, but they must be inserted and removed by a healthcare professional. IUDs provide no protection against sexually transmitted infections, including HIV/AIDS. They are not recommended for women who may be exposed to sexually transmitted infections, such as women with more than one sexual partner. Plan B® can be a useful backup method on those rare occasions when an IUD becomes dislodged or expelled.

Natural Family Planning (Periodic Sexual Abstinence)

Natural family planning (sometimes called "fertility awareness" or "periodic sexual abstinence") generally involves abstaining from vaginal sex during the fertile days of the menstrual cycle. There are a number of different methods. Most couples need some months of training in order to use the methods effectively. Typical pregnancy rates in the first year of use are about 25%. Natural family planning methods provide no protection against sexually transmitted infections, including HIV/AIDS. Plan B® can be used as a backup for natural family planning if, for example, a woman realizes after sex that she has miscalculated the fertile period.

Patch (Transdermal Patch)

One of the newest methods of birth control is a patch that releases low doses of *estrogen* and *progestin*, synthetic versions of naturally occurring female hormones. Women use one patch per week for three weeks, followed by a break for one week. The patch is worn on the abdomen, buttocks, upper arm or upper torso (except on the breasts). The patch prevents pregnancy in the same way birth control pills do, but may be more convenient for some women. The patch has many of the same advantages and disadvantages as the birth control pill. Side effects and pregnancy rates in the first year of use are expected to be similar to that of the pill. The patch requires a prescription. Plan B® can be a useful backup method if you apply a new patch late.

Spermicide

Spermicides are often used with female barrier methods, such as diaphragms, but may also be used alone. Spermicides work by attacking sperm. They are available without a prescription, but must be used each time you have sex. Used alone, they have a typical first year pregnancy rate of 29%. Their main advantage is that they are widely available in pharmacies and can be used without a male partner's cooperation. They do not protect against HIV/AIDS. For women who

Package Insert - Alternate Methods of Birth Control (3)

rely solely on spermicides alone or with a barrier method, Plan B® may be a useful backup if unprotected sex occurs.

Vaginal Ring

Another new method of birth control is the vaginal ring. The ring releases low levels of *estrogen* and *progestin*, synthetic versions of naturally occurring female hormones. The ring is worn inside the vagina continuously for three weeks, followed by a break for one week. It does not need to be removed during sexual intercourse. It works the same way as birth control pills and has many of the same advantages and disadvantages. Side effects and failure rates are expected to be similar. The ring requires a prescription. Plan B® can be a useful backup method if you insert a new vaginal ring late.

Voluntary Sterilization

Contraceptive sterilization for women involves blocking off the fallopian tubes by a variety of means to prevent the passage of eggs and sperm. Male sterilization blocks the passage of sperm. Sterilization is highly effective, with a typical first year pregnancy rate of 0.5% for female sterilization and 0.15% for male sterilization. Advantages of female sterilization may include decreased risk of ovarian cancer. Disadvantages may include increased risk of ectopic pregnancy in the event of failure. Neither male nor female sterilization provide any protection against sexually transmitted infections, including HIV/AIDS. Most methods of sterilization involve minor surgery. Sterilization is a permanent method and should be considered only by women and men who are certain they want no more children.

Sources:

1. Hatcher RA, Nelson MA, Ziemann M et al. *A Pocket Guide to Managing Contraception*. Tiger, Georgia: Bridging the Gap Foundation, 2002.
<http://www.managingcontraception.com/images/pdfs/managing.pdf>
2. Trussell J. Contraceptive failure. In Hatcher RA, Trussell J, Stewart F, et al. *Contraceptive Technology: Eighteenth Revised Edition*. New York NY: Ardent Media, 2004.