



FOR USE WITH CLAM SHELL

PlanB One-Step emergency contraceptive
One Tablet. One Step.

See New Warning NDC 51285-162-88

PlanB One-Step[®]
levonorgestrel 1.5 mg
emergency contraceptive

Reduces chance of pregnancy after unprotected sex.
Not for regular birth control.

1 Tablet Levonorgestrel 1.5 mg

TEVA

Nonvarnish - No Print

TEVA Women's Health

SF FP0

Rev. 7/2017

Visit us at: www.PlanBOneStep.com

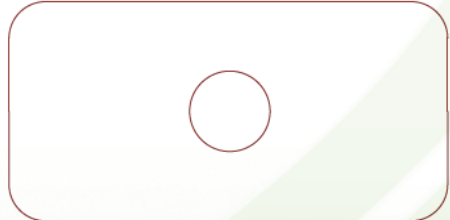
Call 1-800-330-1271 or visit www.PlanBOneStep.com

TEVA
Manufactured by TEVA WOMEN'S HEALTH INC., North Wales, PA 19154
Subsidiary of TEVA PHARMACEUTICALS USA, INC.
Mfg. by Teva Women's Health, Ltd., Budapest, Hungary

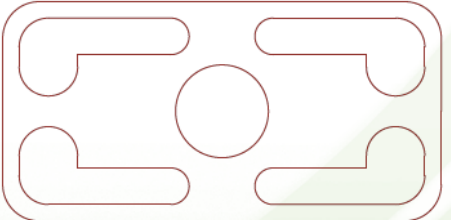
| DRUG FACTS TEXT DEFINED | TYPE SIZE | TYPE FONT |
|---------------------------------------|---------------|--|
| • DRUG FACTS Title | 9 pt | Helvetica Bold Condensed Oblique |
| • DRUG FACTS CONTINUED | n/a | Helvetica Bold Cond. Oblique/Helvetica Condensed |
| • HEADINGS | 8 pt | Helvetica Bold Condensed Oblique |
| • SUBHEADS/BODY TEXT | 6 pt | Helvetica Bold Condensed/Helvetica Condensed |
| • LEADING | 6.5 pt | |
| • # OF CHARACTERS PER INCH | <39 | |
| • BULLETS | 5 pt | Zapf Dingbats |
| • SPACE AFTER BULLETED SECTION | 2 ems | |
| • BARLINES, HAIRLINES | 2.5 pt, .5 pt | |
| • SPACE BETWEEN HAIRLINES AND BOX END | 2 spaces | |

Rev. 7/2017

PlanB One-Step
emergency contraceptive
One Tablet. One Step.



PlanB One-Step
emergency contraceptive
One Tablet. One Step.



- The sooner you take it, the more effective it will be
- Take as soon as possible within 72 hours (3 days) after unprotected sex
- Will not harm an existing pregnancy

PlanB One-Step
1 Tablet Levonorgestrel 1.5 mg

PlanB One-Step
emergency contraceptive

One Tablet. One Step.

The sooner you take it, the more effective it will be

Take as soon as possible within 72 hours (3 days) after unprotected sex

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Nonvarnish - No Print


Visit us at:
www.PlanBOneStep.com

PlanB One-Step
emergency contraceptive

One Tablet. One Step.

FOR CLINIC USE ONLY. NDC 51285-146-19

See New Warning



PlanB One-Step
levonorgestrel 1.5 mg
emergency contraceptive

Reduces chance of pregnancy after unprotected sex. *One Tablet. One Step.*


Not for regular birth control.

1 Tablet Levonorgestrel 1.5 mg

Nonvarnish - No Print

TEAR HERE TO OPEN

9 51285-146-19 3 N



Manufactured by TEVA PHARMACEUTICALS U.S.A., INC., North Wales, PA 19384
 Mfg. by Teva-Brno, Ltd., Brno, Czech Republic
 for TEVA WOMEN'S HEALTH, INC.
 TEVA Women's Health

Drug Facts

| Active ingredient | Purpose |
|-----------------------|-------------------------|
| Levonorgestrel 1.5 mg | Emergency contraceptive |

Use for women to reduce chance of pregnancy after unprotected sex (if a contraceptive failed or if you did not use birth control)

Warnings
Allergy alert: Do not use if you have ever had an allergic reaction to levonorgestrel
Sexually transmitted diseases (STDs) alert: This product does not protect against HIV/AIDS or other STDs

Do not use

- if you are already pregnant (because it will not work)
- for regular birth control

Ask a doctor or pharmacist before use if you are taking efavirenz (HIV medication) or rifampin (tuberculosis treatment) or medication for seizures (epilepsy). These medications may reduce the effectiveness of levonorgestrel.

When using this product you may have

| | | |
|----------------------------------|-------------|---------------|
| ■ menstrual changes | ■ tiredness | ■ breast pain |
| ■ nausea | ■ headache | ■ vomiting |
| ■ lower stomach (abdominal) pain | ■ dizziness | |

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control center right away.

Directions

- take as soon as possible within 72 hours (3 days) after unprotected sex. The sooner you take it the better it will work.
- if you vomit within 2 hours after taking the medication, call a healthcare professional to find out if you should repeat the dose

Other information

- read the instructions, warnings and enclosed product leaflet before use
- this product works mainly by preventing ovulation (egg release). It may also prevent fertilization of a released egg (joining of sperm and egg) or attachment of a fertilized egg to the uterus (implantation).
- do not use if carton is open or tear strip is removed or blister seal is broken or missing
- store at 20-25°C (68-77°F)

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

Questions?
 Call 1-800-330-1271 or visit www.PlanBOneStep.com

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



Reference ID: 4137835

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



Plan B
One-Step

*Reduces chance
of pregnancy after
unprotected sex.*

**Survey of 1000 OB/GYNs, February 2017*

Rev. 8/2017

Reference 1: Data on file, Teva Women's Health, Inc.

Reference ID: 4137835

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 should not be used as regular birth control.

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® will not protect you from HIV infection (the virus that causes AIDS) and other sexually transmitted diseases (STDs).

When should I use Plan B One-Step®?

The sooner you take emergency contraception, the better it works. You should use Plan B One-Step® within 72 hours (3 days) **after you have had unprotected sex**.

Plan B One-Step® is a backup or emergency method of birth control you can use when:

- your regular birth control was used incorrectly or failed
- you did not use any birth control method

When not to use Plan B One-Step®.

Plan B One-Step® should not be used:

- as a regular birth control method, because it's not as effective as regular birth control.
- if you are already pregnant, because it will not work.
- if you are allergic to levonorgestrel or any other ingredients in Plan B One-Step®.

When should I talk to a doctor or pharmacist?

Ask a doctor or pharmacist before use if you are taking efavirenz (HIV medication) or rifampin (tuberculosis treatment) or medication for seizures (epilepsy). These medications may reduce the effectiveness of Plan B One-Step® and increase your chance of becoming pregnant. Your doctor may prescribe another form of emergency contraception that may not be affected by these medications.

How does Plan B One-Step® work?

Plan B One-Step® is one tablet with levonorgestrel, a hormone that has been used in many birth control pills for several decades. 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).

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

You have 72 hours (3 days) to try to prevent pregnancy after birth control failure or unprotected sex. **The sooner you take Plan B One-Step®, the better it works.**

How effective is Plan B One-Step®?

If Plan B One-Step® is taken as directed, it can significantly decrease the chance that you will get pregnant. About 7 out of every 8 women who would have gotten pregnant will not become pregnant.

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

You will know Plan B One-Step® has been effective when you get your next period, which should come at the expected time, or within a week of the expected time. If your period is delayed beyond 1 week, it is possible you may be pregnant. You should get a pregnancy test and follow up with your healthcare professional.

Will I experience any side effects?

- some women may have changes in their period, such as a period that is heavier or lighter or a period that is early or late. **If your period is more than a week late, you may be pregnant.**
- if you have severe abdominal pain, you may have an ectopic pregnancy, and should get immediate medical attention.
- when used as directed, Plan B One-Step® is safe and effective. Side effects may include changes in your period, nausea, lower stomach (abdominal) pain, tiredness, headache, dizziness, and breast tenderness.
- if you vomit within 2 hours of taking the medication, call a healthcare professional to find out if you should repeat the dose.

What if I still have questions about Plan B One-Step®?

If you have questions or need more information, call our toll-free number, 1-800-330-1271, or visit our website at www.PlanBOneStep.com.



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Teva Women's Health
Plan B One-Step

If you are sexually active, you should see a healthcare provider for routine checkups. Your healthcare provider will talk to you about and, if necessary, test you for sexually transmitted diseases, teach you about effective methods of routine birth control, and answer any other questions you may have.

Other Information

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.

Do not use if the blister seal is opened.

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

Active ingredient: levonorgestrel
1.5 mg

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

1-800-330-1271
www.PlanBOneStep.com

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KAREN M MAHONEY
08/10/2017