

## **PLAN B ONE-STEP- levonorgestrel tablet**

### **A-S Medication Solutions**

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## **Plan B One-Step®**

### ***Drug Facts***

#### **Active ingredient**

Levonorgestrel 1.5 mg

#### **Purpose**

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
- 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.

## **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](http://www.PlanBOneStep.com)**

## **CONSUMER INFORMATION**

**Plan B One-Step®**

**Emergency Contraceptive**

**One Tablet. One Step.**

**What You Need to Know**

**Plan B One-Step® Logo**

**Teva Women's Health, 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 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

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<sup>®</sup> worked?**

You will know Plan B One-Step<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>?**

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](http://www.PlanBOneStep.com).

## **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](http://www.PlanBOneStep.com)

**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.**

Manufacturer logo lock up PBOS logo lock up

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## levonorgestrel



### PLAN B ONE-STEP

levonorgestrel tablet

#### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-1141(NDC:51285-146)
Route of Administration	ORAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEVONORGESTREL (UNII: 5W7SIA7YZW) (LEVONORGESTREL - UNII:5W7SIA7YZW)	LEVONORGESTREL	1.5 mg

#### Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, POTATO (UNII: 8I089SAH3T)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TALC (UNII: 7SEV7J4R1U)	
STARCH, CORN (UNII: O8232NY3SJ)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

#### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	G00
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-1141-0	1 in 1 BOX, UNIT-DOSE	11/28/2014	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021998	12/18/2013	

**Labeler** - A-S Medication Solutions (830016429)

### Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-1141)

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A-S Medication Solutions