

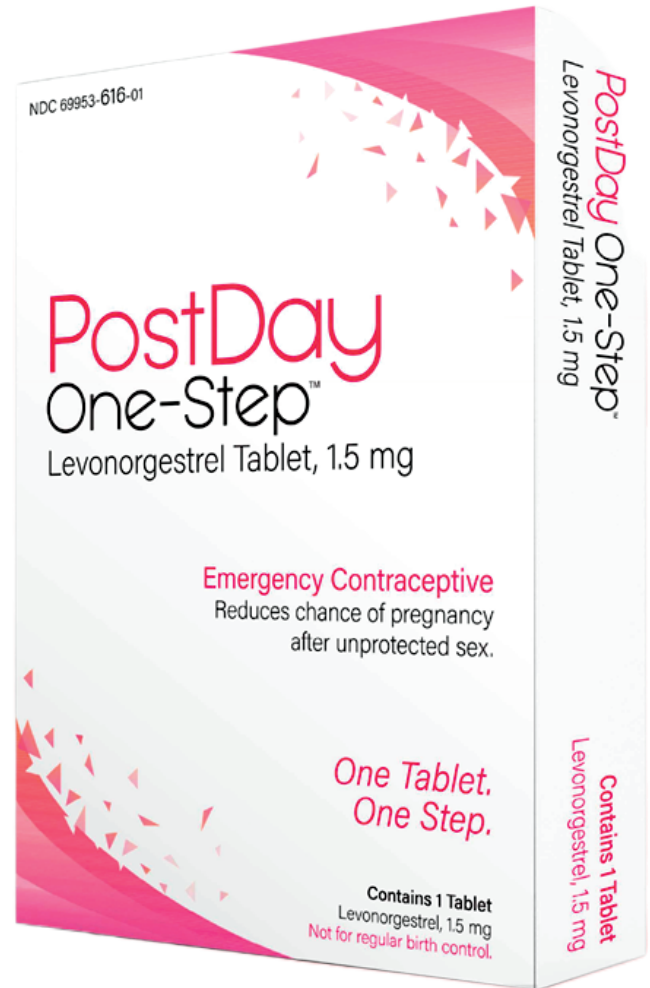


# PostDay<sup>®</sup> One-Step

Levonorgestrel Tablet, 1.5 mg  
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**



Drug Facts	
<b>Active ingredient</b> Levonorgestrel 1.5 mg.....	<b>Purpose</b> Emergency contraceptive
<b>Use</b> for women of all ages to reduce chance of pregnancy after unprotected sex (if a contraceptive failed or if you did not use birth control)	

UNIT BARCODE
3 69953 61601 1

UNIT DIMENSIONS	L x W x H
3.5" x 0.6" x 5"	
UNIT WEIGHT	LBS
0.12 lbs.	

MASTER CASE				
PACK	DIMENSIONS (L x W x H)	WEIGHT	CASE CUBE	TI:HI
12	8" x 6" x 4"	1.85 lbs	0.11	40 x 12



## 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 (1-800-222-1222) 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 the blister seal is broken or missing
- store at 20° to 25°C (68° to 77°F)

## INACTIVE INGREDIENTS

colloidal silicon dioxide, corn starch, lactose monohydrate, magnesium stearate, potato starch and talc.

## QUESTIONS?

Call 1-855-274-4122

Mfg for Rapha Pharmaceuticals, Inc.

Orlando, Florida 32819 USA

Made in India

## PATIENT INFORMATION

**PostDay One-Step™**

**(levonorgestrel tablet, 1.5 mg)**

**Emergency Contraceptive One Tablet.**

**One Step.**

**What You Need to Know**

### **What is PostDay One-Step™?**

PostDay 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 PostDay One-Step™ is not.**

PostDay One-Step™ will not work if you are already pregnant and will not affect an existing pregnancy. PostDay One-Step™ will not protect you from HIV infection (the virus that causes AIDS) and other sexually transmitted diseases (STDs).

### **When should I use PostDay One-Step™?**

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

### **PostDay 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 PostDay One-Step™.

PostDay 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 PostDay 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 PostDay 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 PostDay One-Step™ work?

PostDay One-Step™ is one tablet with levonorgestrel, a hormone that has been used in many birth control pills for several decades. PostDay 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 PostDay 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 PostDay One-Step™?

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

## How effective is PostDay One-Step™?

If PostDay 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 PostDay One-Step™ worked?

You will know PostDay 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, PostDay 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 PostDay One-Step™?

If you have questions or need more information, call our toll-free number at 1-855-274-4122.



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## 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° to 25°C (68° to 77°F).

**Active ingredient:** levonorgestrel 1.5 mg

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

**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.**

Manufactured for:

**Rapha Pharmaceuticals, Inc.**

Orlando, Florida 32819 USA

Manufactured by:

**Aurobindo Pharma Limited**

Hyderabad-500 038, India

Revised: 02/2018

## PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1.5 MG (1 TABLET CARTON LABEL)

**NDC 69953-616-01**

**PostDay One-Step™**

**(levonorgestrel tablet 1.5 mg)**

**Emergency Contraceptive**

**Reduces chance of pregnancy after unprotected sex.**

**Contains 1 Tablet Levonorgestrel 1.5 mg**

**Not for regular birth control.**

**One Tablet.**

**One Step.**

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

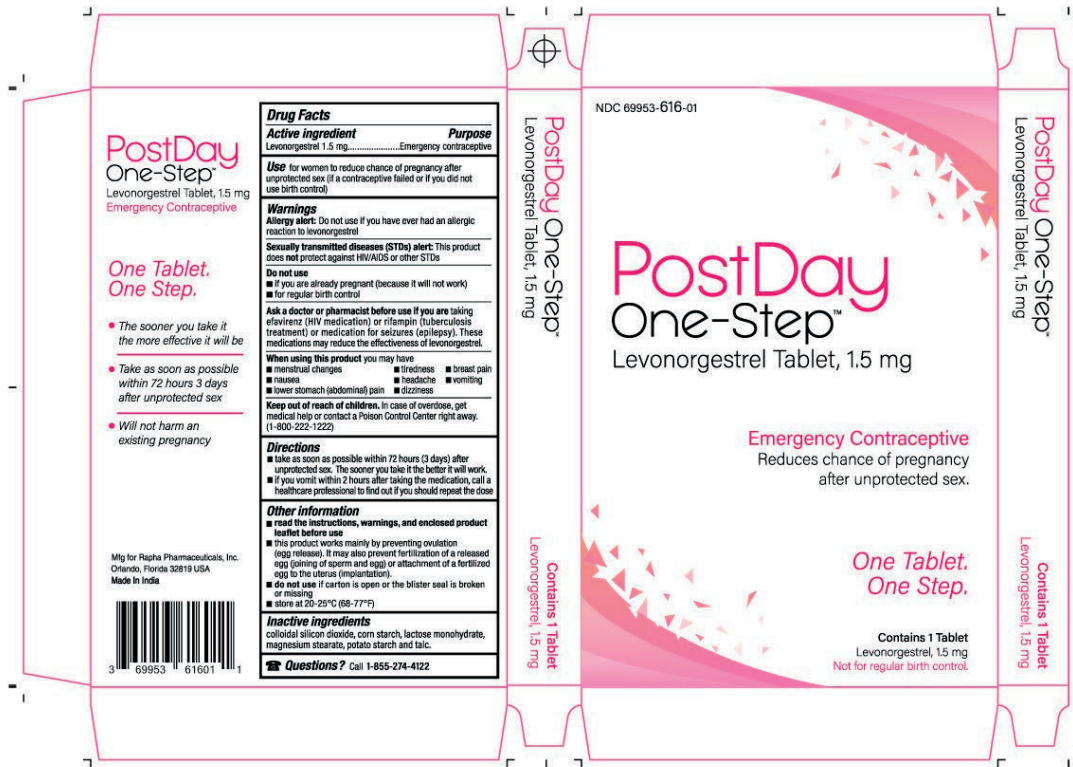
**Take as soon as possible within 72 hours (3 days) after unprotected sex**

**Will not harm an existing pregnancy**

**New! Now Available Over The Counter**



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## POSTDAY ONE-STEP

levonorgestrel tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69953-616
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

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

7887 Dunbrook Rd Suite H, San Diego CA 92126  
info@biolabsinternational.net | (800) 440-4580





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### Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	S;11
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69953-616-01	1 in 1 CARTON	07/01/2018	
1		1 mg in 1 BLISTER PACK; Type 0: Not a Combination Product		

**Labeler** - Rapha Pharmaceuticals, Inc. (079804155)

Revised: 6/2018

**Authorized distributor for United States.  
Serving, Government services, Hospitals and Medical Distributors**

**BIOLABS INTERNATIONAL LLC**

**info@biolabsinternational.net**

**(800) 440-4580**

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