

LEVONORGESTREL- levonorgestrel tablet
Rugby Laboratories

Levonorgestrel

Drug Facts

Active ingredient

Levonorgestrel, USP 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
- tiredness
- dizziness
- nausea
- headache
- breast pain
- lower stomach (abdominal) pain
- vomiting

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

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° to 25°C (68° to 77°F)

Inactive ingredients

colloidal silicon dioxide, corn starch, hypromellose, lactose monohydrate, magnesium stearate, talc

Questions or comments?

For more information, call toll free 1-800-818-4555 weekdays

Distributed by:

Rugby Laboratories, 17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152

PRINCIPAL DISPLAY PANEL - 1.5 mg Tablet Blister Pack Carton

NDC 0536-1142-63

Rugby[®]

**COMPARE TO
active ingredient in
PLAN B ONE-STEP^{®†}**

See New Warning

Levonorgestrel Tablet

1.5 mg

Emergency Contraceptive

- **Reduces the chance of pregnancy after unprotected sex**
- **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**
- **Not for regular birth control**

1 Tablet Levonorgestrel 1.5 mg

ONE TABLET. ONE STEP.

Levonorgestrel Tablet

1.5 mg

Emergency Contraceptive
ONE TABLET. ONE STEP.

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Distributed by:
Rugby Laboratories, 17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152
www.rugbylaboratories.com
MADE IN INDIA Rev. 11/17 Re-Order No. 370667 R-34

Lot No.

Expiration Date:

NON VARNISH



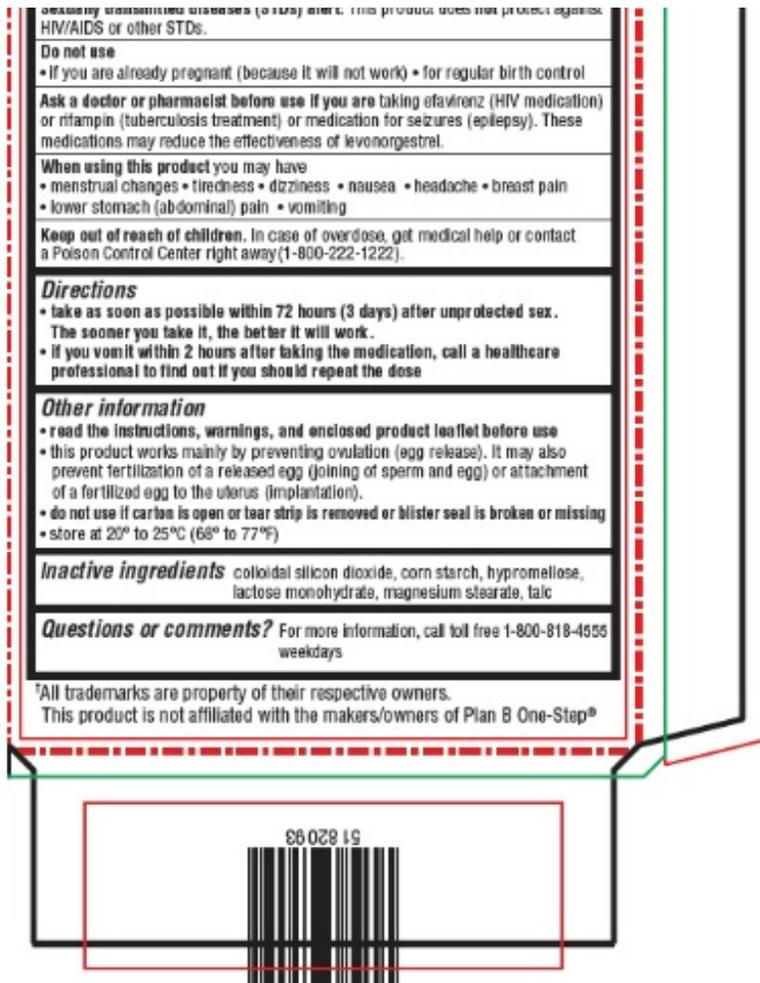
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Levonorgestrel, USP 1.5 mg.....	Emergency contraceptive

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



LEVONORGESTREL

levonorgestrel tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1142
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, corn (UNII: O8232NY3SJ)	
hypromellose, unspecified (UNII: 3NXW29V3WO)	
lactose monohydrate (UNII: EWQ57Q8I5X)	
magnesium stearate (UNII: 70097M6I30)	
talc (UNII: 7SEV7J4RIU)	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1142-63	1 in 1 CARTON	11/01/2017	
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
ANDA	ANDA202635	11/01/2017	

Labeler - Rugby Laboratories (079246066)**Establishment**

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Limited		725959238	MANUFACTURE(0536-1142)

Revised: 4/2018

Rugby Laboratories