LEADER EMERGENCY CONTRACEPTIVE LEVONORGESTREL-
levonorgestrel tablet
Cardinal Health 110, LLC. DBA Leader

LEADER

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 1-800-406-7984 weekdays

DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017

PRINCIPAL DISPLAY PANEL - 1.5 mg Tablet Blister Pack Carton

LEADER™

NDC 70000-0600-1

Levonorgestrel

Tablet, 1.5 mg
Emergency Contraceptive

Reduces the Chance of Pregnancy
after Unprotected Sex

Not for Regular Birth Control

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

One Tablet, One Step

COMPARE TO
PLAN B ONE-STEP®
active ingredient†

100% Money
Back Guarantee

1 LEVONORGESTREL TABLET

SEE NEW WARNING

LEADER

Levonorgestrel

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NDC 70000-0600-1

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Actual Size

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SEE NEW WARNING

Levonorgestrel

Tablet, 1.5 mg
Emergency Contraceptive

LEADER

DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017
www.myleader.com
1-800-200-6313

Made in India

100% Money Back Guarantee
Return to place of purchase if not satisfied.

REV. 4/22

CIN 5774583

0 96295 14192 4

Lot No.

Expiration Date:

NON VARNISH

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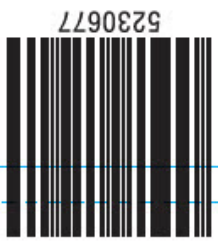
†This product is not manufactured or distributed by Foundation Consumer Healthcare, owner of the registered trademark Plan B One-Step®.



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LEADER EMERGENCY CONTRACEPTIVE LEVONORGESTREL

levonorgestrel tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70000-0600
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: 7SEV7J4R1U)	

Product Characteristics			
Color	WHITE (white to off-white)	**Score**	no score
Shape	ROUND (circular)	**Size**	8mm
Flavor		**Imprint Code**	718
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70000-0600-1	1 in 1 CARTON	03/22/2022	
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	03/22/2022	

Labeler - Cardinal Health 110, LLC. DBA Leader (063997360)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Limited		725959238	MANUFACTURE(70000-0600)

Revised: 6/2022 Cardinal Health 110, LLC. DBA Leader