

EMERGENCY CONTRACEPTIVE- levonorgestrel tablet
Cardinal Health (Leader) 70000

EContra One-Step®
(Levonorgestrel) Tablet 1.5 mg

Active ingredient (in each tablet)

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 medication may reduce the effectiveness of levonorgestrel.

When using the product you may have

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

Keep out of reach 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 package is open or blister seal is broken or missing**
- store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

Inactive ingredients

croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, poloxamer 188

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal display panel

COMPARE TO PLAN B ONE-STEP® active ingredient*

Levonorgestrel Tablet 1.5 mg

Emergency Contraceptive

Reduces chances 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

Tablet

*This product is not manufactured or distributed by Foundation Consumer Healthcare LLC, distributor of Plan B One Step®.

DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017

Package label

LEADER™

NDC 70000-0647-1

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

CONTAINS 1 TABLET 1.5 mg

PLD-A470A FC008711

Lot No.:
Exp. Date:

Cardinal Health™
DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43007
www.levoneur.com 1-800-206-6333
Essential to Care since 1919
Product of Italy

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Drug Facts

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LEADER Emergency Contraceptive 1.5 mg

EMERGENCY CONTRACEPTIVE

levonorgestrel tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0647(NDC:70700-164)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEVONORGESTREL (UNII: 5W7SIA7YZ W) (LEVONORGESTREL - UNII:5W7SIA7YZ W)	LEVONORGESTREL	1.5 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLOXAMER 188 (UNII: LQA7B6G8JG)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	C;1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0647-1	1 in 1 CARTON	09/15/2023	
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	ANDA205329	09/15/2023	

Labeler - Cardinal Health (Leader) 70000 (063997360)

Revised: 9/2023

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