

EMPOWERED CHOICE- levonorgestrel 1.5 mg tablet
Versea Diagnostics

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

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?

Call **1-800-397-0670**

SPL UNCLASSIFIED SECTION

Distributed by:

Versea Diagnostics, LLC

Tampa, FL 33602

PRINCIPAL DISPLAY PANEL

NDC 83567-7003-5

*Compare to the active ingredient of Plan B One-Step[®]

EMPOWERED CHOICE[™]

Levonorgestrel Tablet 1.5 mg

Emergency Contraceptive

1 Tablet Levonorgestrel 1.5 mg

One Tablet. One Step.

- 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

NDC 83567-7003-5

*Compare to the active ingredient of Plan B One-Step®.

See New Warning

Empowered Choice™

Emergency Contraceptive

Levonorgestrel Tablet, 1.5 mg

One Tablet.

One Step. 

Reduces chances of pregnancy after unprotected sex

Not for regular birth control

Contains 1 Tablet
Levonorgestrel Tablet, 1.5 mg

Empowered Choice™



EMPOWERED CHOICE

levonorgestrel 1.5 mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83567-7003
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
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
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:83567-7003-5	1 in 1 CARTON	09/01/2023	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

NDC 83567-7003-5

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See New Warning

Empowered Choice™

Emergency Contraceptive

Levonorgestrel Tablet, 1.5 mg

One Tablet.

One Step. 

Reduces chances of pregnancy after unprotected sex

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Contains 1 Tablet

Levonorgestrel Tablet

Empowered Choice™

Tablet, 1.5 mg

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202635	08/25/2023	

Labeler - Versea Diagnostics (118736277)

Revised: 7/2023

Versea Diagnostics