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 af ter unprotected sex (if a contraceptive failed or if you did not use bir th 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

 st Compare to the active ingredient of Plan B One-Step ltimes

EMPOWERED CHOICE TM

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®.

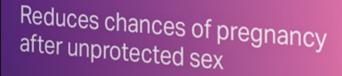
See New Warning

Empowered Choice™

Emergency Contraceptive

Levonorgestrel Tablet, 1.5 mg

One Tablet.
One Step.



Not for regular birth control

Contains 1 Tablet Levonorgestrel Tablet, 1.5 mg

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: 5W7SIA7YZW) (LEVONORGESTREL - UNII:5W7SIA7YZW)	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

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

See New Warning

Empowered Choice[™]

Emergency Contraceptive

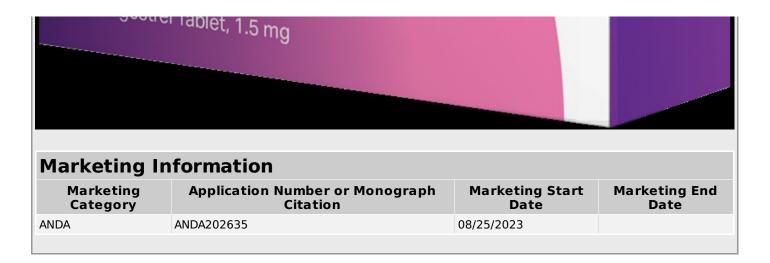
Levonorgestrel Tablet, 1.5 mg

One Tablet. One Step.

Reduces chances of pregnancy after unprotected sex

Not for regular birth control

Contains 1 Tablet Levonorgestrel Tab



Labeler - Versea Diagnostics (118736277)

Revised: 7/2023 Versea Diagnostics