

LEVONORGESTREL- levonorgestrel tablet
OC Pharma, LLC

Levonorgestrel Tablets

Drug Facts

Active ingredient

Levonorgestrel 1.5mg

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

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.

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 of taking the medication, call a healthcare professional to find out if you should repeat that 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 the carton is open or blister seal is broken or missing**
- store at 20° to 25°C (68° to 77°F)

Inactive ingredients

colloidal silicon dioxide, FD&C Yellow No.6 aluminum lake, lactose monohydrate, magnesium stearate, and pregelatinized starch

Questions or comments?

Call 1-800-224-4606.

PRINCIPAL DISPLAY PANEL - 1.5 mg Tablet Blister Pack Carton

NDC 49615-017-01

Levonorgestrel Tablet

1.5 mg

Emergency Contraceptive

Reduces chance of pregnancy after unprotected sex.

Not for regular birth control.

ONE TABLET. ONE DOSE.

OC

Pharma

Contains 1 Levonorgestrel Tablet 1.5 mg

- **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.**



LEVONORGESTREL

levonorgestrel tablet

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:496 15-0 17

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)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
Lactose Monohydrate (UNII: EWQ57Q8I5X)	
Magnesium Stearate (UNII: 70097M6I30)	
Starch, corn (UNII: O8232NY3SJ)	

Product Characteristics

Color	ORANGE	Score	no score
Shape	ROUND	Size	8 mm
Flavor		Imprint Code	17
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49615-017-01	1 in 1 CARTON	12/31/2018	
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	ANDA202380	12/01/2018	

Labeler - OC Pharma, LLC (171268936)

Revised: 10/2017

OC Pharma, LLC