

LEVONORGESTREL- levonorgestrel tablet
Curae Pharma360 Inc.

Levonorgestrel

Drug Facts

Active ingredient

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 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 at 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 of 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 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 1-888-885-3054 Monday - Friday 9 AM - 5 PM EST

Manufactured for:
Curae Pharma360 Inc.
San Francisco, CA 94105
NDC 73358-911-01
Product made in Germany
Rev. September 2022

PRINCIPAL DISPLAY PANEL - 1.5 mg Tablet Blister Pack Carton

NDC 73358-911-01

Levonorgestrel Tablet
1.5 mg

Emergency Contraceptive

Curae™
Pharma360

Reduce 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.

Contains 1 levonorgestrel tablet

Levonorgestrel Tablet

1.5 mg

Emergency Contraceptive

NDC 73358-911-01

Levonorgestrel Tablet

1.5 mg

Emergency Contraceptive

Curae[™]
Pharma360

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Not for regular birth control.

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ONE TABLET.
ONE STEP.

Contains 1 levonorgestrel tablet

51751189
Code 1811

Levonorgestrel Tablet

1.5 mg

Emergency Contraceptive

This package is not
child-resistant

67x19x102



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San Francisco, CA 94105
Product made in Germany
Issue: September 2022

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control center right away at 1-800-222-1222.

When using this product you may have:
■ lower stomach (abdominal) pain ■ dizziness
■ nausea ■ headache ■ vomiting
■ menstrual changes ■ tiredness ■ breast pain

medications may reduce the effectiveness of levonorgestrel. Ask a doctor or pharmacist before use if you are taking (HIV medication) or rifampin (tuberculosis treatment) or medication for seizures (epilepsy). These

■ for regular birth control
■ if you are already pregnant (because it will not work)
Do not use

does not protect against HIV/AIDS or other STDs
Sexually transmitted diseases (STDs) alert: This product

reaction to levonorgestrel
Allergy alert: Do not use if you have ever had an allergic

Use for women to reduce chance of pregnancy after unprotected sex (if a contraceptive failed or if you did not use birth control)

Levonorgestrel 1.5 mg Emergency contraceptive
Purpose

Drug Facts
Active ingredient

Drug Facts (continued)

■ 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 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).

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min.
6 mm



min.
6 mm

LEVONORGESTREL

levonorgestrel tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73358-911
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
Lactose Monohydrate (UNII: EWQ57Q8I5X)	
Starch, Corn (UNII: O8232NY3SJ)	
Magnesium Stearate (UNII: 70097M6I30)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Fd&C Yellow No. 6 (UNII: H77VEI93A8)	

Product Characteristics

Color	ORANGE (Light peach)	Score	no score
Shape	ROUND (Round convex)	Size	8mm
Flavor		Imprint Code	17
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73358-911-01	1 in 1 CARTON	10/17/2022	
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	ANDA202380	10/17/2022	

Labeler - Curae Pharma360 Inc. (080719852)

Registrant - Naari Pte. Limited (659345996)

Revised: 10/2022

Curae Pharma360 Inc.