

EMERGENCY CONTRACEPTIVE- levonorgestrel tablet
P & L Development, LLC

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 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 (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 the active ingredient in Plan B One-Step®†

emergency contraceptive

levonorgestrel

Tablet 1.5 mg

one tablet. one step.

- 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

reduces chance of pregnancy after unprotected sex not for regular birth control

tablet 1.5 mg

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

Distributed by:

PL Developments
200 Hicks Street
Westbury, NY 11590

Package Label

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

<p>Drug Facts (continued)</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.</p>	<p>Active ingredient (in each tablet) Levonorgestrel 1.5 mg.....Emergency contraceptive</p>
<p>Directions</p> <p>Take as soon as possible within 72 hours (3 days) after unprotected sex. The sooner you take it the better it will work.</p> <p>If you vomit within 2 hours after taking the medication, call a healthcare professional to find out if you should repeat the dose.</p>	<p>Use for women to reduce chance of pregnancy after unprotected sex (if a contraceptive failed or if you did not use birth control)</p> <p>Warnings</p> <p>Allergy alert: Do not use if you have ever had an allergic reaction to levonorgestrel</p> <p>Sexually transmitted diseases (STDs) alert: This product does not protect against HIV/AIDS or other STDs</p> <p>Do not use</p> <ul style="list-style-type: none"> if you are already pregnant (because it will not work) for regular birth control
<p>Other information</p> <ul style="list-style-type: none"> 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]. 	<p>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.</p> <p>When using this product you may have</p> <ul style="list-style-type: none"> menstrual changes nausea lower stomach (abdominal) pain headache dizziness breast pain vomiting
<p>Inactive ingredients croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyoxamer 188</p>	<p>Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST</p>

emergency contraceptive
levonorgestrel
tablet 1.5 mg



Compare to the active ingredient in
Plan B One-Step®†

NDC 59726-138-01

emergency contraceptive
levonorgestrel
tablet 1.5 mg

one tablet. one step.

- 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

**reduces chance of pregnancy after unprotected sex
not for regular birth control**

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t No.:
p. Date:

contains 1 tablet 1.5 mg

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Distributed by:
PL Developments
200 Hicks Street
Westbury, NY 11590



READYinCASE Emergency Contraceptive

EMERGENCY CONTRACEPTIVE

levonorgestrel tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-138(NDC:70700-164)
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
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:59726-138-01	1 in 1 CARTON	08/01/2023	
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	08/01/2023	

Labeler - P & L Development, LLC (800014821)

Revised: 6/2023

P & L Development, LLC