

PLAN B ONE-STEP- levonorgestrel tablet
Foundation Consumer Healthcare LLC

Plan B One-Step®

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.

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**
- **do not use if carton is open or tear strip is removed or blister seal is broken or missing**
- store at 20-25°C (68-77°F)

Inactive ingredients

colloidal silicon dioxide, corn starch, lactose monohydrate, magnesium stearate, potato starch, talc

Questions?

Call **1-800-330-1271** or visit www.PlanBOneStep.com

Distributed by:
Foundation Consumer Healthcare, LLC. (FCH)
Pittsburgh, PA 15205

PRINCIPAL DISPLAY PANEL - 1.5 mg Tablet Blister Pack Box - NDC 69536-162-88

NDC 69536-162-88

This item is
electronically
protected

Plan B
One-Step®

levonorgestrel 1.5 mg

emergency contraceptive

Reduces chance of
pregnancy after
unprotected sex.

Not for regular birth control.

One Tablet.

One Step.

1 Tablet Levonorgestrel 1.5 mg

NDC 69536-162-88



PlanB One-Step

emergency contraceptive
One Tablet. One Step.

FCH

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**One Tablet.
One Step.**



1 Tablet Levonorgestrel 1.5 mg

TEAR HERE TO OPEN



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Rev. 11/2022



PlanB One-Step

emergency contraceptive

**One Tablet.
One Step.**

The sooner you take it, the more effective it will be

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Will not harm an existing pregnancy

Visit us at:
www.PlanBOneStep.com

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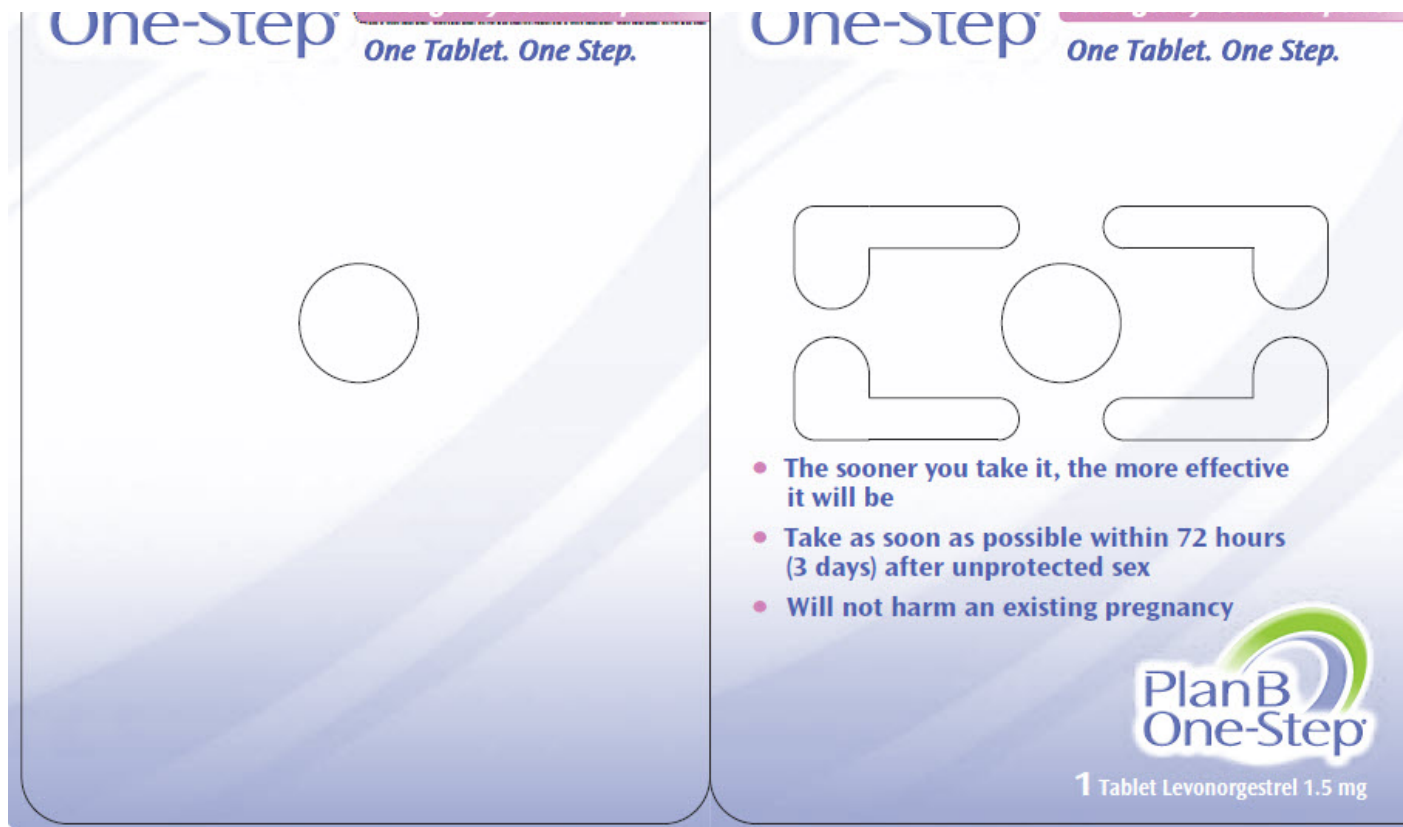
Made in Germany
Distributed by:
Eaton Consumer Care, LLC (ECC)
Arlington, VA 22202



emergency contraceptive



emergency contraceptive



PRINCIPAL DISPLAY PANEL - 1.5 mg Tablet Blister Pack Box - NDC 69536-146-19

FOR CLINIC USE ONLY.
NOT FOR RETAIL SALE.

NDC 69536-146-19

Plan B
One-Step®

levonorgestrel 1.5 mg

emergency contraceptive

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One Tablet.
One Step.

1 Tablet Levonorgestrel 1.5 mg

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NDC 69536-146-19

PlanB
One-Step

emergency contraceptive
One Tablet. One Step.

FCH

PlanB One-Step[®]

levonorgestrel 1.5 mg

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**One Tablet.
One Step.**



1 Tablet Levonorgestrel 1.5 mg

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Rev. 11/2022

PlanB One-Step
emergency contraceptive
One Tablet. One Step.
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PlanB
One-Step

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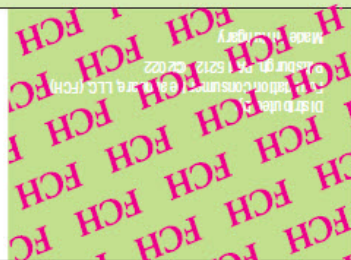
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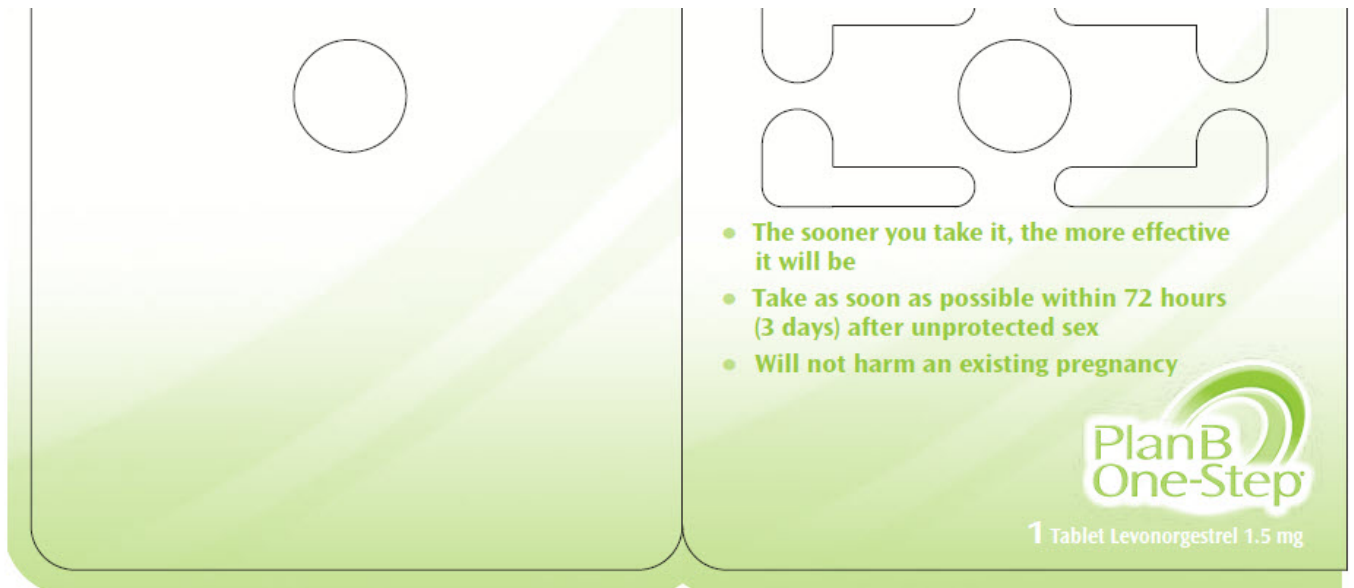


Plan B One-Step

emergency contraceptive
One Tablet. One Step.

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PLAN B ONE-STEP

levonorgestrel tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69536-162
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)	
STARCH, POTATO (UNII: 8I089SAH3T)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TALC (UNII: 7SEV7J4R1U)	
STARCH, CORN (UNII: O8232NY3SJ)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	G00
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69536-162-88	1 in 1 BOX, UNIT-DOSE	05/10/2018	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:69536-162-99	1 in 1 BOX, UNIT-DOSE	08/15/2019	
2		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
NDA	NDA021998	05/10/2018	

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TALC (UNII: 7SEV7J4R1U)	
STARCH, CORN (UNII: O8232NY3SJ)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

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Labeler - Foundation Consumer Healthcare LLC (079675882)

Revised: 1/2023

Foundation Consumer Healthcare LLC