

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**
- 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 20-25°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

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[®]

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

TEAR HERE TO OPEN



79930101177

799-30-101177

Rev. 03/2018



Drug Facts

Active ingredient	Purpose
Levonorgestrel 1.5 mg.....	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)

PlanB One-Step[®]

PI

emergency
contraceptive

**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**

Visit us at:
www.PlanBOneStep.com

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
- nausea
- lower stomach (abdominal) pain
- tiredness
- headache
- vomiting
- breast 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
- 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 20-25°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



emergency contraceptive
One Tablet. One Step.

FCH



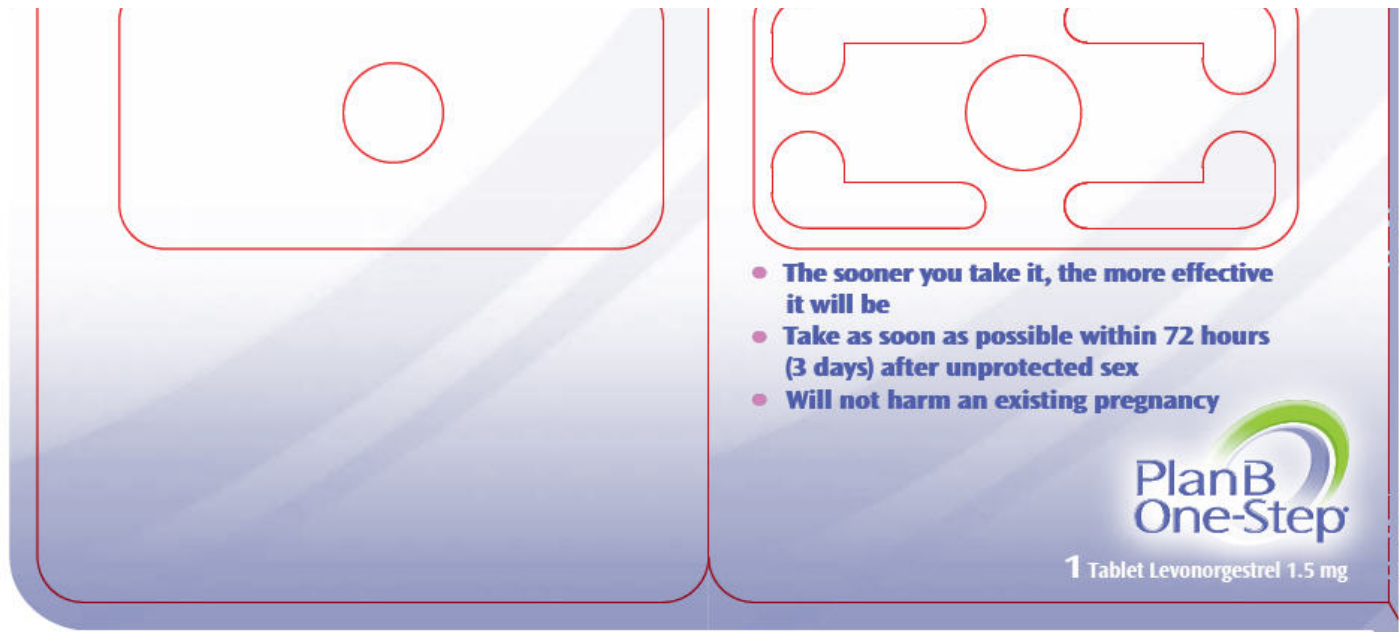
It is obtained by
F. Hoffmann-Laurance, LLC, (FCH)
Pittsburgh, PA 15205 ©2018
Made in Hungary



emergency contraceptive
One Tablet. One Step.



emergency contraceptive
One Tablet. One Step.



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

Reduces chance of
pregnancy after
unprotected sex.

Not for regular birth control.

One Tablet.

One Step.

1 Tablet Levonorgestrel 1.5 mg

FOR CLINIC USE ONLY.
NOT FOR RETAIL SALE.

NDC 69536-146-19

PlanB
One-Step

emergency contraceptive

One Tablet. One Step.

FCH

PlanB 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

TEAR HERE TO OPEN



79930101176

799-30-101176

Rev. 03/2018

emergency contraceptive
One Tablet. One Step.

PlanB
One-Step

1

PlanB One-Step

emergency
contraceptive

**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**

Visit us at:
www.PlanBOneStep.com

Drug Facts

Active ingredient	Purpose
Levonorgestrel 1.5 mg.....	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

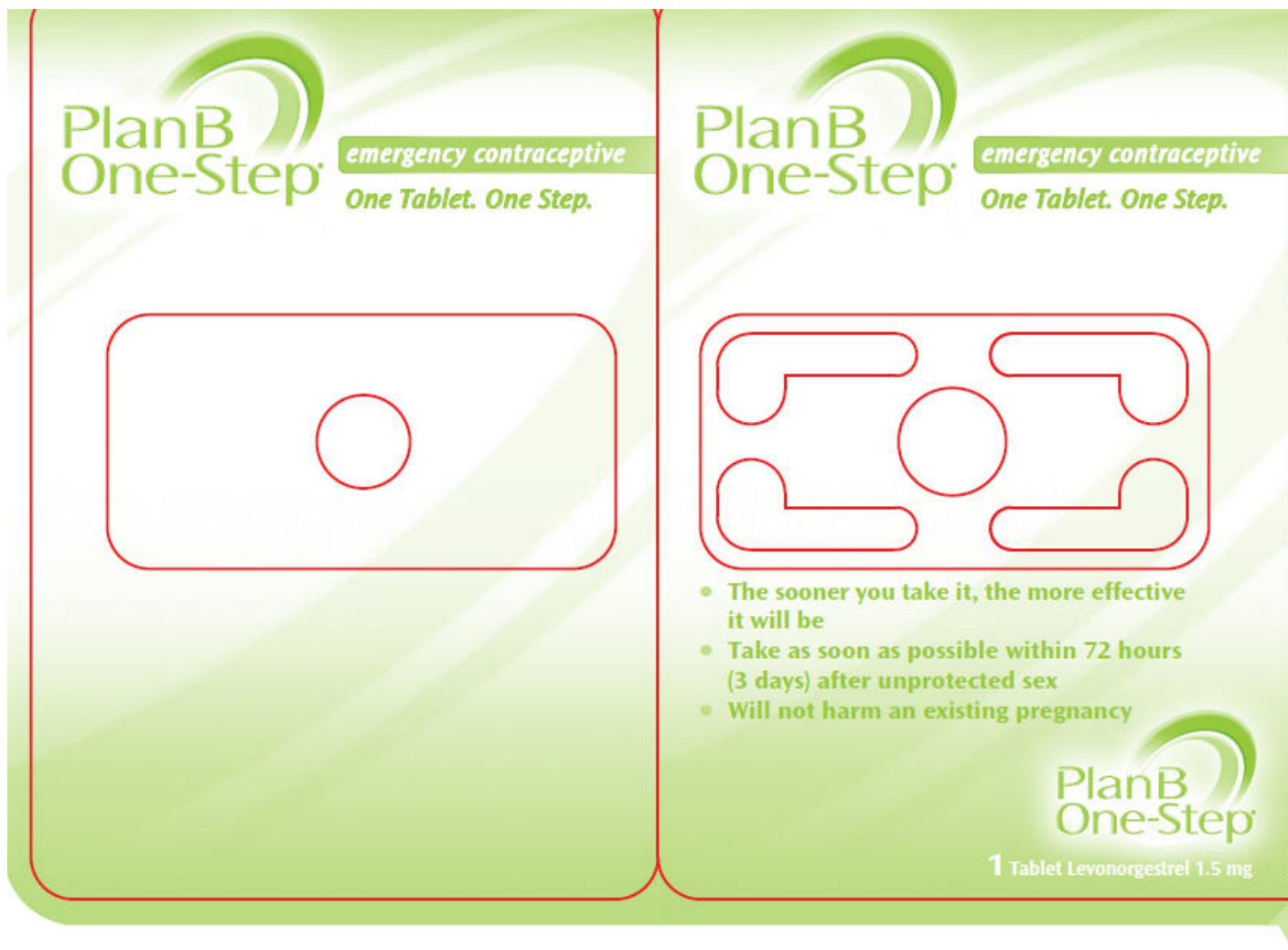
- read the instructions, warnings and enclosed product leaflet before use
- this product works mainly by preventing ovulation (egg release). It may also prevent fertilization of a released egg (joining of sperm and egg) or attachment of a fertilized egg to the uterus (implantation).
- do not use if carton is open or tear strip is removed or blister seal is broken or missing
- store at 20-25°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



Made in Hungary
Pittsburgh, PA 15205 ©2018
Foundation Consumer Healthcare, LLC (FCH)
Distributed by:



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: 8I089SAHBT)	
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	

PLAN B ONE-STEP

levonorgestrel tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69536-146
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: 8I089SAHBT)	
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:69536-146-19	1 in 1 BOX, UNIT-DOSE	05/10/2018	
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
NDA	NDA021998	05/10/2018	

Labeler - Foundation Consumer Healthcare LLC (079675882)

Revised: 8/2019

Foundation Consumer Healthcare LLC