

AFTERA- levonorgestrel tablet
Foundation Consumer Healthcare LLC

Aftera®

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 **1-888-919-0780**

Manufactured by:
Gedeon Richter, Ltd., Budapest, Hungary

PRINCIPAL DISPLAY PANEL - 1.5 mg Tablet Blister Pack Box

NDC 69536-103-88

Emergency Contraceptive
COMPARE TO PLAN B ONE-STEP®

Aftera®

LEVONORGESTREL 1.5 mg

Reduces chance of pregnancy
after unprotected sex.

One Tablet.

One Dose.

NOT FOR REGULAR BIRTH CONTROL

1 Tablet

Levonorgestrel

1.5 mg

Aftera[®]
LEVONORGESTREL 1.5 mg

NDC 69536-103-88

Emergency Contraceptive
COMPARE TO PLAN B ONE-STEP[®]

One Tablet. One Dose.
Emergency Contraceptive

Aftera[®]
LEVONORGESTREL 1.5 mg

Reduces chance of pregnancy
after unprotected sex.

NOT FOR REGULAR BIRTH CONTROL

One Tablet.
One Dose.

1 Tablet
Levonorgestrel
1.5 mg

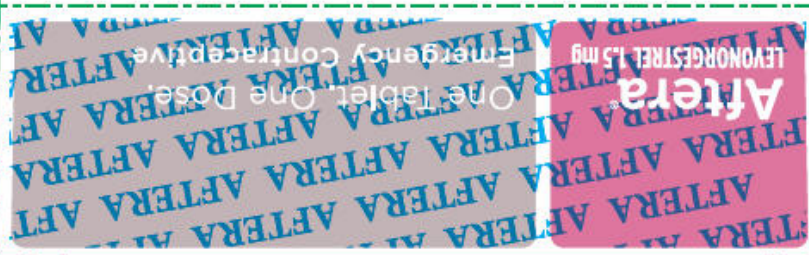
TEAR HERE TO OPEN



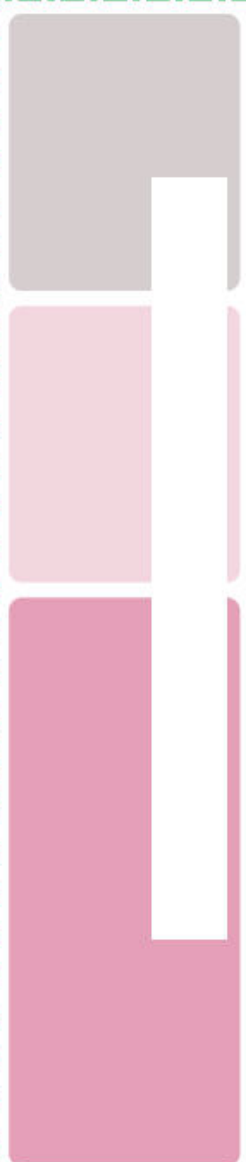
799301 01180

799-30-101180

Rev. 03/2018



1



Emergency Contraceptive

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

Aftera®
LEVONORGESTREL 1.5 mg

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.

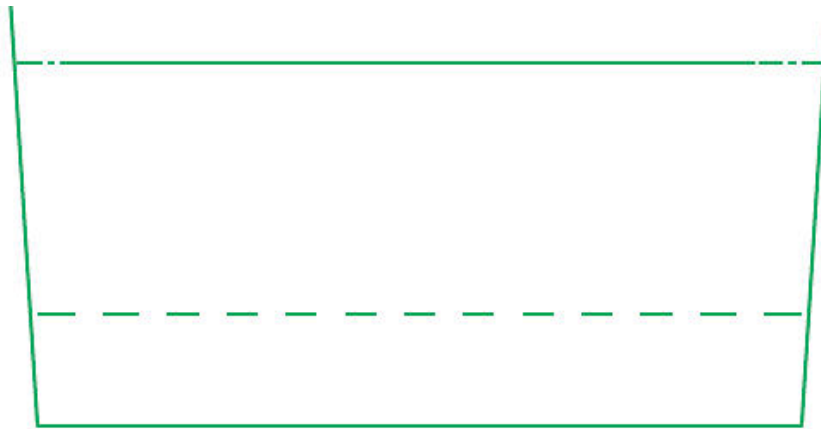
Directions
 ■ take as soon as possible within 72 hours (3 days) after unprotected sex. The sooner you take it the better it will work.
 ■ if you vomit within 2 hours after taking the medication, call a healthcare professional to find out if you should repeat the dose

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 1-888-919-0780

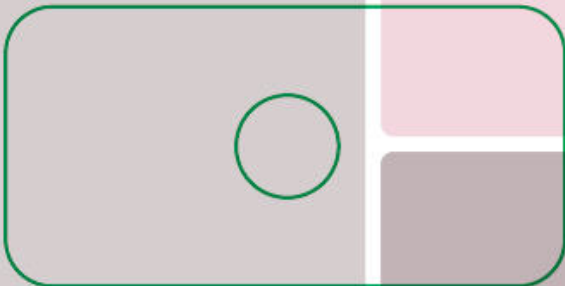




Aftera[®]
LEVONORGESTREL 1.5 mg

One Tablet.
One Dose.

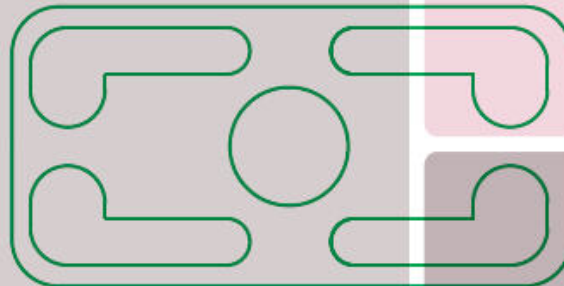
Emergency
Contraceptive



Aftera[®]
LEVONORGESTREL 1.5 mg

One Tablet.
One Dose.

Emergency
Contraceptive



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

AFTERA			
levonorgestrel tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69536-103
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:69536-103-88	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 AUTHORIZED GENERIC	NDA021998	05/10/2018		

Labeler - Foundation Consumer Healthcare LLC (079675882)

Revised: 10/2019

Foundation Consumer Healthcare LLC