

MORNING AFTER- levonorgestrel tablet
Rapha Pharmaceuticals, Inc.

Active Ingredient

Levonorgestrel 1.5 mg

Purpose

Emergency contraceptive

Use

for women 17 years of age and older to reduce chance of pregnancy after unprotected sex (if a contraceptive failed or if you did not use birth control)

Warnings

Keep out of reach of children

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- women 17 years of age or older:
- 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 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, povidone

Questions or comments?

Call 1-800-719-9260

Consumer Information

Levonorgestrel Tablet, 1.5 mg
Emergency Contraceptive

One Tablet. One Step.

What You Need to Know

What is Levonorgestrel Tablet, 1.5 mg?

Levonorgestrel Tablet, 1.5 mg is emergency contraception that helps prevent pregnancy after birth control failure or unprotected sex. It is a backup method of preventing pregnancy and should not be used as regular birth control.

What Levonorgestrel Tablet, 1.5 mg is not.

Levonorgestrel Tablet, 1.5 mg will not work if you are already pregnant and will not affect an existing pregnancy. Levonorgestrel Tablet, 1.5 mg will not protect you from HIV infection (the virus that causes AIDS) and other sexually transmitted diseases (STDs).

When should I use Levonorgestrel Tablet, 1.5 mg?

The sooner you take emergency contraception, the better it works. You should use Levonorgestrel Tablet, 1.5 mg within 72 hours (3 days) after you have had unprotected sex.

Levonorgestrel Tablet, 1.5 mg is a backup or emergency method of birth control you can use when:

- your regular birth control was used incorrectly or failed
- you did not use any birth control method

When not to use Levonorgestrel Tablet, 1.5 mg.

Levonorgestrel Tablet, 1.5 mg should not be used:

- as a regular birth control method, because it's not as effective as regular birth control.
- if you are already pregnant, because it will not work.
- if you are allergic to levonorgestrel or any other ingredients in Levonorgestrel Tablet, 1.5 mg.

How does Levonorgestrel Tablet, 1.5 mg work?

Levonorgestrel Tablet, 1.5 mg is one tablet with levonorgestrel, a hormone that has been used in many birth control pills for several decades. Levonorgestrel Tablet, 1.5 mg contains a higher dose of levonorgestrel than birth control pills, but works in a similar way to prevent pregnancy. It works mainly by stopping the release of an egg from the ovary. It is possible that Levonorgestrel Tablet, 1.5 mg may also work by preventing fertilization of an egg (the uniting of sperm with the egg) or by preventing attachment (implantation) to the uterus (womb).

How can I get the best results from Levonorgestrel Tablet, 1.5 mg?

You have 72 hours (3 days) to try to prevent pregnancy after birth control failure or unprotected sex. The sooner you take Levonorgestrel Tablet, 1.5 mg, the better it works.

How effective is Levonorgestrel Tablet, 1.5 mg?

If Levonorgestrel Tablet, 1.5 mg is taken as directed, it can significantly decrease the chance that you will get pregnant. About 7 out of every 8 women who would have gotten pregnant will not become pregnant.

How will I know Levonorgestrel Tablet, 1.5 mg worked?

You will know Levonorgestrel Tablet, 1.5 mg has been effective when you get your next period, which should come at the expected time, or within a week of the expected time. If your period is delayed beyond 1 week, it is possible you may be pregnant. You should get a pregnancy test and follow up with your healthcare professional.

Will I experience any side effects?

- some women may have changes in their period, such as a period that is heavier or lighter or a period that is early or late. If your period is more than a week late, you may be pregnant.
- if you have severe abdominal pain, you may have an ectopic pregnancy, and should get immediate medical attention.
- when used as directed, Levonorgestrel Tablet, 1.5 mg is safe and effective. Side effects may include changes in your period, nausea, lower stomach (abdominal) pain, tiredness, headache, dizziness, and breast tenderness.
- if you vomit within 2 hours of taking the medication, call a healthcare professional to find out if you

should repeat the dose.

What if I still have questions about Levonorgestrel Tablet, 1.5 mg?

If you have questions or need more information, call our toll-free number, 1-800-719-9260.

Other information

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.

Do not use if the blister seal is opened.

Store at room temperature 20-25°C (68-77°F).

Active ingredient: levonorgestrel 1.5 mg

Inactive ingredients: colloidal silicon dioxide, corn starch, lactose monohydrate, magnesium stearate, povidone

1-800-719-9260

If you are sexually active, you should see a healthcare provider for routine checkups. Your healthcare provider will talk to you about it and, if necessary, test you for sexually transmitted diseases, teach you about effective methods of routine birth control, and answer any other questions you may have.

Mfg for Rapha Pharmaceuticals, Inc.

Orlando, Florida 32819 USA

Made in India

: 0C312 MF C1

Package/Label Principal Display Panel

Now Available Over The Counter

Morning After™

Levonorgestrel Tablet, 1.5 mg
emergency contraceptive

Reduces chance of pregnancy after unprotected sex.

Not for regular birth control.

One Tablet

One Step

Actual Size

CONTAINS 1 TABLET LEVONORGESTREL 1.5 MG



MORNING AFTER			
levonorgestrel tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69953-514
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	LEVONORGESTREL (UNII: 5W7SIA7YZW) (LEVONORGESTREL - UNII:5W7SIA7YZW)	LEVONORGESTREL	1.5 mg in 1.5 mg
Inactive Ingredients			
	Ingredient Name	Strength	
	LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
	MAGNESIUM STEARATE (UNII: 70097M6I30)		
	POVIDONE (UNII: FZ989GH94E)		
	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
	STARCH, CORN (UNII: O8232NY3SJ)		

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	L0C3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69953-514-01	1 in 1 CARTON	08/21/2016	
1		1 mg 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	ANDA202334	08/21/2016	

Labeler - Rapha Pharmaceuticals, Inc. (079804155)**Registrant** - Rapha Pharmaceuticals, Inc. (079804155)

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Rapha Pharmaceuticals, Inc.