MORNING AFTER- levonorgestrel tablet
Rapha Pharmaceuticals, Inc.

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
- nausea
- lower stomach (abdominal) pain
- tiredness
- headache
- dizziness
- breast pain
- vomiting

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 carton is open or tear strip is removed or the blister seal is broken or missing
- store at 20° to 25°C (68° to 77°F)

INACTIVE INGREDIENTS

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

QUESTIONS?

Call **1-855-274-4122**

Mfg for Rapha Pharmaceuticals, Inc.
Orlando, Florida 32819 USA
Made in India

Code: TS/DRUGS/22/2009

PATIENT INFORMATION

Morning After®
(levonorgestrel tablet, 1.5 mg)
Emergency Contraceptive
One Tablet. One Step.
What You Need to Know

What is Morning After®?
Morning After® 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 Morning After® is not.
Morning After® will not work if you are already pregnant and will not affect an existing pregnancy. Morning After® will not protect you from HIV infection (the virus that causes AIDS) and other sexually transmitted diseases (STDs).

When should I use Morning After®?
The sooner you take emergency contraception, the better it works. You should use Morning After® within 72 hours (3 days) **after you have had unprotected sex.**

Morning After® 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 Morning After®.
Morning After® 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 Morning After®.

When should I talk to a doctor or pharmacist?
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 Morning After® and increase your chance of becoming pregnant. Your doctor may prescribe another form of emergency contraception that may not be affected by these medications.

How does Morning After® work?
Morning After® is one tablet with levonorgestrel, a hormone that has been used in many birth control pills for several decades. Morning After® 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 Morning After® 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 Morning After®?
You have 72 hours (3 days) to try to prevent pregnancy after birth control failure or unprotected sex. **The sooner you take Morning After®, the better it works.**

How effective is Morning After®?
If Morning After® 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 Morning After® worked?
You will know Morning After® 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, Morning After® 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 Morning After®?
If you have questions or need more information, call our toll-free number at 1-855-274-4122.

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° to 25°C (68° to 77°F).

Active ingredient: levonorgestrel 1.5 mg

Inactive ingredients: colloidal silicon dioxide, corn starch, lactose monohydrate, magnesium stearate, potato starch, and talc.

If you are sexually active, you should see a healthcare provider for routine checkups. Your healthcare provider will talk to you about 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.

Manufactured for:
Rapha Pharmaceuticals, Inc.
Orlando, Florida 32819 USA

Manufactured by:
Aurobindo Pharma Limited
Hyderabad-500 038, India

Revised: 02/2018

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1.5 MG (1 TABLET CARTON LABEL)

NDC 69953-515-01
Morning After®
(levonorgestrel tablet 1.5 mg)
Emergency Contraceptive
Reduces chance of pregnancy after unprotected sex.

Contains 1 Tablet Levonorgestrel 1.5 mg
Not for regular birth control.

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
New! Now Available Over The Counter

MORNING AFTER

levonorgestrel tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69953-515
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**
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

TALC (UNII: 7SEV7J4R1U)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STARCH, POTATO (UNII: 8I089SAH3T)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	white	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	S;11
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69953-515-01	1 in 1 CARTON	03/22/2018	
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	ANDA206867	03/22/2018	

Labeler - Rapha Pharmaceuticals, Inc. (079804155)

Revised: 3/2018 Rapha Pharmaceuticals, Inc.