MY WAY- levonorgestrel tablet
Proficient Rx LP

My Way®
(levonorgestrel) Tablet, 1.5 mg

Drug Facts

Active Ingredient

Levonorgestrel USP 1.5 mg

Purpose

Emergency contraceptive

Indications

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 the 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 blister seal is broken or missing** .
- store at 25°C (77°C); excursions permitted to 15 to 30°C (59 to 86°C) [see USP Controlled Room temperature].

Inactive Ingredients

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

Questions or comments?

For more information or to speak to a healthcare professional, call at 1-800-422-8689 M-F 8:00 am - 5:00 pm or visit our website at www.mywaypill.com.

My Way®

(levonorgestrel) Tablet, 1.5 mg

Emergency Contraceptive

One Tablet. One Dose.

What You Need to Know

What is My Way®?

My Way 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 My Way is not.

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

When should I use My Way?

The sooner you take emergency contraception, the better it works. You should use My Way within 72 hours (3 days) **after you have had unprotected sex**.

My Way 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 My Way?

My Way 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 My Way.

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 My Way 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 My Way work?

My Way is one tablet with levonorgestrel, a hormone that has been used in many birth control pills for several decades. My Way 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 My Way 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 My Way?

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

How effective is My Way?

If My Way 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 My Way worked?

You will know My Way 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, My Way 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 My Way?

If you have questions or need more information, call at 1-800-422-8689 M-F 8:00 am - 5:00 pm or visit our website at www.mywaypill.com.

Other Information

Keep this and all medication 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 seal is opened.

Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F) [see USP Controlled Room Temperature].

Active Ingredient: levonorgestrel 1.5 mg

Inactive Ingredients: colloidal silicon dioxide, corn starch, lactose monohydrate, magnesium stearate, and povidone.

My Way® is a registered trademark of Lupin Pharmaceuticals, Inc.

Manufactured for:

Lupin Pharmaceuticals, Inc.

Baltimore, MD 21202

United States

Manufactured by:

Lupin Limited

Pithampur (M.P.) - 454 775

INDIA

Relabeled by:

Proficient Rx LP

Thousand Oaks, CA 91320

Revised: October 2017 ID#: 253401

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.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

My Way®(levonorgestrel) Tablet, 1.5 mg

NDC 71205-361-01

Single Pack- Carton Label: 1 blister containing 1 Tablet

MY WAY

levonorgestrel tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71205-361(NDC:68180-852)
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**
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE K30 (UNII: U725QWY32X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	WHITE (white to off white)	**Score**	no score
Shape	ROUND (round biconvex)	**Size**	9mm
Flavor		**Imprint Code**	LU;S25
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71205-361-01	1 in 1 CARTON	11/18/2019	
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
ANDA	ANDA201446	04/25/2017	

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(71205-361) , RELABEL(71205-361)

Revised: 11/2019 Proficient Rx LP