

MY WAY- levonorgestrel tablet
Lupin Pharmaceuticals, Inc.

Drug Facts

Active Ingredient

Levonorgestrel 1.5mg

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

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 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 20-25°C (68-77°F)

Inactive ingredients

colloidal silicon dioxide, pregelatinized starch, lactose monohydrate, magnesium stearate and talc

Questions?

For more information or to speak to a healthcare professional, call 1-800-422-8689 or visit our website at www.mywaypill.com

My Way

Emergency Contraceptive

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 .

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 1-800-422-8689, or visit our website at www.mywaypill.com

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, pregelatinized starch, lactose monohydrate, magnesium stearate, 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 by:

Novel Laboratories, Inc.

Somerset, NJ 08873

PI6223000201

Rev. 02/2014

PRINCIPAL DISPLAY PANEL

My Way (levonorgestrel) Tablet , 1.5 mg

NDC 43386-622-30

emergency contraceptive

Reduces chance of pregnancy after unprotected sex.

Not for regular birth control.

Contains 1 Tablet 1.5mg

Front Panel

NDC 43386-622-30

My Way[®]

(Levonorgestrel)
Tablet, 1.5 mg

Emergency Contraceptive

Reduces the chance
of pregnancy after
unprotected sex



ONE TABLET
EQUALS
ONE DOSE

**Not for regular
birth control**

1 Tablet Levonorgestrel 1.5mg

Back Panel

My Way[®]

(Levonorgestrel) Tablet, 1.5 mg

The sooner you take My Way[®], the more effective it will be

Take as soon as possible within 72 hours (3 days) after unprotected sex

My Way[®] will not harm an existing pregnancy

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

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Drug Facts (continued)

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Inactive ingredients colloidal silicon dioxide, pregelatinized starch, lactose monohydrate, magnesium stearate, and talc

Questions or comments?

For more information or to speak to a healthcare professional, call 1-800-422-8689 M-F 8:00 am – 5:00 pm.

Visit our website at www.mywaypill.com

GAVIS
PHARMACEUTICALS

A LUPIN GROUP COMPANY

Mfg. for Lupin Pharmaceuticals, Inc., Baltimore, MD 21202

CAA6223000206 Rev 02/2016



MY WAY

levonorgestrel tablet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:43386-622 |
| 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, CORN (UNII: O8232NY3SJ) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| TALC (UNII: 7SEV7J4R1U) | |

Product Characteristics

| | | | |
|----------|-------------------|--------------|----------|
| Color | WHITE (off-white) | Score | no score |
| Shape | ROUND | Size | 8mm |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--------------------------------------------------|----------------------|--------------------|
| 1 | NDC:43386-622-30 | 1 in 1 CARTON; Type 0: Not a Combination Product | 02/15/2013 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| ANDA | ANDA202508 | 02/15/2013 | |

Labeler - Lupin Pharmaceuticals, Inc. (089153071)**Registrant** - GAVIS Pharmaceuticals, LLC (829838551)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|----------------------------------------------|
| Novel Laboratories, Inc. | | 793518643 | analysis(43386-622) , manufacture(43386-622) |