

LEVONORGESTREL- levonorgestrel tablet
Novel Laboratories, Inc.

Drug Facts

Active Ingredient

Levonorgestrel 1.5mg

Purpose

Emergency contraceptive

Use for women to reduce the 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 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

Levonorgestrel Tablet

Emergency Contraceptive

What You Need to Know

What is Levonorgestrel Tablet?

Levonorgestrel Tablet 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 is not.

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

When should I use Levonorgestrel Tablet?

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

Levonorgestrel Tablet 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.

Levonorgestrel Tablet 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.

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 Levonorgestrel Tablet 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 Levonorgestrel Tablet work?

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

You have 72 hours (3 days) to try to prevent pregnancy after birth control failure or unprotected sex.

The sooner you take Levonorgestrel Tablet, the better it works.

How effective is Levonorgestrel Tablet?

If Levonorgestrel Tablet 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 worked?

You will know Levonorgestrel Tablet 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 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?

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

Manufactured by:

Novel Laboratories, Inc

Somerset, NJ 08873

P16223000102 Rev. 09/2017

1-800-422-8689 www.mywaypill.com

PRINCIPAL DISPLAY PANEL

Levonorgestrel Tablet, 1.5 mg

NDC 40032-622-30

emergency contraceptive

Reduces chance of pregnancy after unprotected sex.

Not for regular birth control.

Contains 1 Tablet 1.5mg



Mfg by: Novel Laboratories
Somerset, NJ 08873
CAA6223000105 Rev. 09/2017

Questions or comments?
For more information or to speak to a healthcare professional, call 1-800-422-6689, M-F 8:00 am - 5:00 pm. Visit our website at www.mynwaypill.com

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

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)

Drug Facts (continued)
■ If you vomit within 2 hours after taking the medication, call a healthcare professional to find out if you should repeat the dose

Directions
■ take as soon as possible within 72 hours (3 days) after unprotected sex. The sooner you take it the better it will work.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.
■ lower stomach (abdominal) pain ■ vomiting ■ nausea ■ headache ■ breast pain ■ menstrual changes ■ dizziness ■ dizziness
When using this product you may have effectiveness of levonorgestrel.

Ask a doctor or pharmacist before use if you are taking any other birth control, ■ for regular birth control ■ if you are already pregnant (because it will not work) ■ if you are already pregnant (because it will not work)

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

Use for women to reduce chance of pregnancy after unprotected sex (if a contraceptive failed or if you did not use birth control)

Purpose Levonorgestrel 1.5 mg ... Emergency contraceptive

Drug Facts



Levonorgestrel Tablet
The sooner you take levonorgestrel tablet, 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

Levonorgestrel Tablet 1.5 mg

Emergency Contraceptive

NDC 40032-622-30

Levonorgestrel Tablet 1.5 mg

Emergency Contraceptive



Reduces the chance of pregnancy after unprotected sex
Not for regular birth control.

1 Tablet Levonorgestrel 1.5 mg

Levonorgestrel Tablet 1.5 mg
Emergency Contraceptive

Area for Lot & Expiration Date

Levonorgestrel Tablet 1.5 mg

Emergency Contraceptive

LEVONORGESTREL

levonorgestrel tablet

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:40032-622 |
| 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:40032-622-30 | 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 - Novel Laboratories, Inc. (793518643)

Registrant - Novel Laboratories, Inc. (793518643)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------|---------|--------|---------------------|
|------|---------|--------|---------------------|

| | | |
|--------------------------|-----------|--|
| Novel Laboratories, Inc. | 793518643 | ANALYSIS(40032-622) , MANUFACTURE(40032-622) , PACK(40032-622) |
|--------------------------|-----------|--|

Revised: 9/2017

Novel Laboratories, Inc.