

LEVONORGESTREL- levonorgestrel tablet
Xiromed LLC

Levonorgestrel Tablet 1.5 mg

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

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- | | | |
|----------------------------------|-------------|---------------|
| • menstrual changes | • tiredness | • breast pain |
| • nausea | • headache | • vomiting |
| • lower stomach (abdominal) pain | • dizziness | |
-

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**
- **do not use if carton is open or blister seal is broken or missing**
- store at 20-25°C (68-77°F)

Inactive ingredients

croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, poloxamer 188

Questions?

Call **1-844-947-6633** Monday-Friday 9AM-5PM EST

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.

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 1.5 mg work?

Levonorgestrel tablet 1.5 mg works before release of an egg from the ovary. As a result, levonorgestrel tablet usually stops or delays the release of an egg from the ovary. Levonorgestrel tablet is one tablet that contains a higher dose of levonorgestrel than birth control pills and works in a similar way to prevent pregnancy.

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, 1-844-947-6633, or visit our website at www.xiromed.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 20–25°C (68–77°F)

Active ingredient: levonorgestrel 1.5 mg

Inactive ingredients: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, poloxamer 188

1-844-947-6633

www.xiromed.com

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.

XIROMED, LLC.

Levonorgestrel tablet 1.5 mg

Manufactured by:
Laboratorios León Farma S.A.
C/La Vallina s/n
Poligono Industrial de
Navatejera
24008 Villaquilambre, León,
Spain

Manufactured for:
Xiromed, LLC.
Florham Park, NJ 07932

164-06-01 Rev. 09/2023

Principle Display Panel - Blister



The image shows a principle display panel for a blister pack of Levonorgestrel Tablet 1.5 mg. The panel is divided into two identical sections, one above the other. Each section contains the following text and graphics:

- One Tablet One Step*
- Levonorgestrel Tablet 1.5 mg**
- Reduces chance of pregnancy after unprotected sex
- emergency contraceptive**
- Made in Spain
- MFD. FOR XIROMED, LLC.
- FLORHAM PARK, NJ 07932
- Barcode with numbers 3 70700 16406 8
- 164-06-00 (L) (EXP)
- Rev. 12/2019

The entire panel is enclosed in a rounded rectangular border with a dashed line on the right side, indicating the blister pack's edge.

Principle Display Panel - Carton

Levonorgestrel Tablet
(levonorgestrel) tablet 1.5 mg
Emergency contraceptive
Reduces chance of pregnancy after unprotected sex.
Not for regular birth control.
Xiromed LLC.



LEVONORGESTREL

levonorgestrel tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70700-164
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

Cellulose, Microcrystalline (UNII: OP1R32D61U)	
Lactose Monohydrate (UNII: EWQ57Q8I5X)	
Croscarmellose Sodium (UNII: M28OL1HH48)	
Poloxamer 188 (UNII: LQA7B6G8JG)	
Magnesium Stearate (UNII: 70097M6I30)	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	C;1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70700-164-06	1 in 1 CARTON	03/13/2020	
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	ANDA205329	03/13/2020	

Labeler - Xiromed LLC (080228637)

Registrant - Xiromed Pharma España, S.L (468835741)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratorios León Farma S.A.		467782459	manufacture(70700-164) , analysis(70700-164) , pack(70700-164)

Revised: 9/2023

Xiromed LLC