

SHEWISE- levonorgestrel tablet
GLENMARK THERAPEUTICS INC., USA

Levonorgestrel Tablet

Drug Facts

Active ingredient

Levonorgestrel, USP 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 disease (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 tear strip is removed or blister seal is broken or missing**
- Store at room temperature, 20°C to 25°C (68°F to 77°F)

Inactive ingredients

Colloidal silicon dioxide, corn starch, lactose monohydrate, magnesium stearate, potato starch, talc

Questions or comments?

Call 1 (888) 721-7115 or visit www.glenmarkpharma-us.com

Levonorgestrel Tablet 1.5 mg Emergency Contraceptive One Tablet, One Dose 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 our toll-free number 1 (888) 721-7115 or visit our website at www.glenmarkpharma-us.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°C to 25°C (68°F to 77°F).

Active ingredient: levonorgestrel, USP 1.5 mg

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

Glenmark Pharmaceuticals Limited

Colvale-Bardez, Goa 403513, India

Manufactured for:

Glenmark Therapeutics Inc., USA

Mahwah, NJ 07430

Questions? 1 (888) 721-7115

www.glenmarkpharma-us.com

May 2022

Principal Display Panel



152904921934

UNWASHED AREA
70mm x 20mm
FOR LOT & EXP.

SheWise™ Levonorgestrel Tablet 1.5 mg



EMERGENCY CONTRACEPTIVE

Drug Facts

Active ingredient **Purpose**
Levonorgestrel, USP 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

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 • headache • lower stomach (abdominal) pain • breast pain
- nausea • dizziness • tiredness • 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 tear strip is removed or blister seal is broken or missing.
- Store at room temperature, 20°C to 25°C (68°F to 77°F).

Inactive ingredients

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

Questions or comments?

Call 1 (888) 721-7115 or visit www.glenmarkpharma.us.com

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

EMERGENCY CONTRACEPTIVE

Contains 1 Tablet, 1.5 mg



EMERGENCY CONTRACEPTIVE

Contains 1 Tablet, 1.5 mg

EMERGENCY CONTRACEPTIVE

Contains 1 Tablet, 1.5 mg



726571081216

This product is not manufactured or distributed by Foundation Consumer Healthcare, LLC, distributor of Plan B One-Step®, and owner of the registered trademark Plan B One-Step® [Foundation Consumer Healthcare, LLC does not make or license Glenmark's product].

*Compare to the active ingredient of Plan B One-Step®

NDC 72657-108-12

SheWise™
Levonorgestrel Tablet 1.5 mg

EMERGENCY CONTRACEPTIVE



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

Contains 1 Tablet, 1.5 mg



Manufactured for:
Glenmark Therapeutics Inc., USA
Northwall, NJ 07430
06/22

Manufactured by: **Glenmark Pharmaceuticals Limited**
Connaught Place,
Gurgaon-122002, India
GO/DRUGS/785

This package is not child resistant.

*Compare to the active ingredient of Plan B One-Step®

EMERGENCY CONTRACEPTIVE

Contains 1 Tablet, 1.5 mg

SheWise™
Levonorgestrel Tablet 1.5 mg



Package/Label Principal Display Panel



SHEWISE

levonorgestrel tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72657-108
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEVONORGESTREL (UNII: 5W7SIA7YZ W) (LEVONORGESTREL - UNII:5W7SIA7YZ W)	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)	
STARCH, POTATO (UNII: 8I089SAH3T)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	WHITE (off-white)	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	G;78
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72657-108-12	1 in 1 CARTON	07/29/2022	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:72657-108-11	1 in 1 CARTON	07/29/2022	
2		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	ANDA207044	07/29/2022	

Labeler - GLENMARK THERAPEUTICS INC., USA (969085666)

Establishment

Name	Address	ID/FEI	Business Operations
Glenmark Pharmaceuticals Limited		677318665	MANUFACTURE(72657-108) , ANALYSIS(72657-108)

Revised: 7/2022

GLENMARK THERAPEUTICS INC., USA