

OPTIONELLE - levonorgestrel tablet, 1.5 mg tablet
Strides Pharma Inc

OPTIONELLE
(Levonorgestrel Tablet 1.5 mg)
Emergency Contraceptive

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

- 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 at 1-800-222-1222.

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° to 25°C (68° to 77°F)

Inactive ingredients

colloidal silicon dioxide, FD&C Yellow No. 6 aluminum lake, lactose monohydrate, magnesium stearate, and pregelatinized starch

Questions or comments?

Call 1-877-244-9825.

Manufactured for:

Strides Pharma Inc.

East Brunswick, NJ 08816

Product made in Germany

Issued: September 2022

OPTIONELLE

Levonorgestrel Tablet 1.5 mg

- **Emergency Contraceptive**
- **One Tablet. One Step.**
- **What You Need To Know**

What is Optionelle?

Optionelle 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 Optionelle is not.

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

When should I use Optionelle?

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

Optionelle 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 Optionelle.

Optionelle 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 Optionelle.

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 Optionelle 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 Optionelle work?

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

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

How effective is Optionelle?

If Optionelle 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 Optionelle worked?

You will know Optionelle 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, Optionelle 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 Optionelle?

If you have questions or need more information, call our toll free number, 1-877-244-9825.

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° to 77°F).

Active ingredient: levonorgestrel 1.5 mg

Inactive ingredients: colloidal silicon dioxide, FD&C Yellow No. 6 aluminum lake, lactose monohydrate, magnesium stearate, and pregelatinized starch

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 for:

Strides Pharma Inc.

East Brunswick, NJ 08816

Product made in Germany.

NDC 59556-286-01 Rev. September 2022

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

OPTIONELLE

Levonorgestrel Tablet 1.5 mg

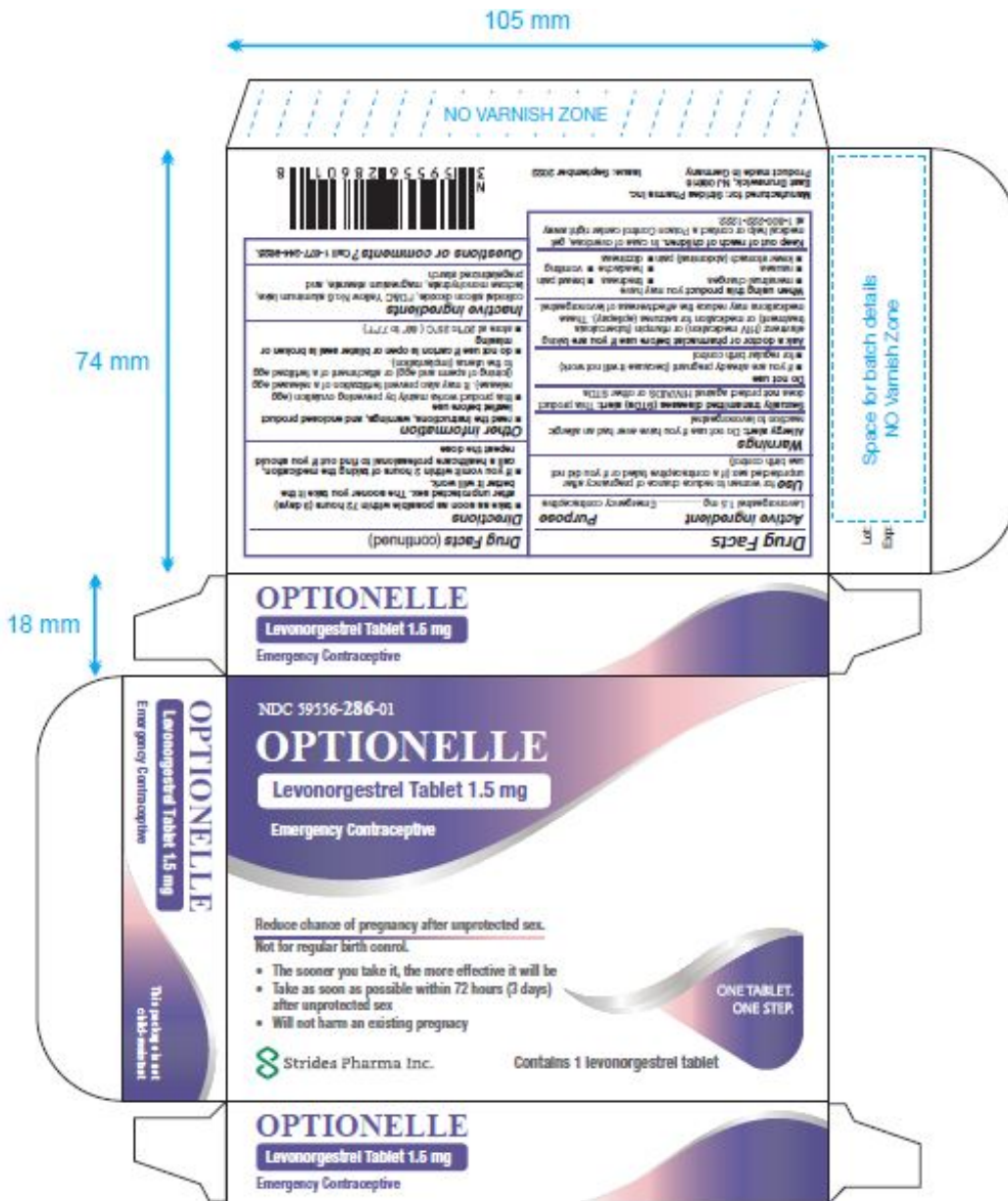
Emergency Contraceptive

Reduces chance of pregnancy after unprotected sex.

Not for regular birth control.

ONE TABLET. ONE STEP.

Contains 1 levonorgestrel tablet



OPTIONELLE

levonorgestrel tablet, 1.5 mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59556-286
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)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
Product Characteristics				
Color	ORANGE (Light peach)	Score	no score	
Shape	ROUND	Size	8mm	
Flavor		Imprint Code	17	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59556-286-01	1 in 1 CARTON	09/15/2022	
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	ANDA202380	09/15/2022		

Labeler - Strides Pharma Inc (078868278)

Registrant - Naari Pte. Limited (659345996)

Establishment

Name	Address	ID/FEI	Business Operations
Haupt Pharma Muenster GmbH		344172564	ANALYSIS(59556-286) , MANUFACTURE(59556-286)