

OPCICON ONE-STEP - levonorgestrel tablet
Sun Pharmaceutical Industries, Inc.

Opcicon™ One-Step

Active ingredient

Levonorgestrel, USP 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.

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 tear strip is removed or blister seal is broken or missing**
- store at 20° to 25°C (68° to 77°F)

Inactive ingredient

colloidal silicon dioxide, corn starch, hypromellose, lactose monohydrate, magnesium stearate, talc

Questions or comments?

For more information, call toll free 1-800-818-4555 weekdays

Opcicon™ One-Step

(levonorgestrel) Tablet, 1.5 mg

Emergency Contraceptive

One Tablet. One Step.

What You Need to Know

What is Opcicon™ One-Step?

Opcicon™ One-Step 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 Opcicon™ One-Step is not.

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

When should I use Opcicon™ One-Step?

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

Opcicon™ One-Step 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 Opcicon™ One-Step.

Opcicon™ One-Step 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 Opcicon™ One-Step.

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 Opcicon™ One-Step 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 Opcicon™ One-Step work?

Opcicon™ One-Step works before release of an egg from the ovary. As a result, Opcicon™ One-Step usually stops or delays the release of an egg from the ovary. Opcicon™ One-Step 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 Opcicon™ One-Step?

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

works.

How effective is Opcicon™ One-Step?

If Opcicon™ One-Step 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 Opcicon™ One-Step worked?

You will know Opcicon™ One-Step 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, Opcicon™ One-Step 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 Opcicon™ One-Step?

If you have questions or need more information, call our toll-free number, 1-800-818-4555.

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° to 25°C (68° to 77°F).

Active ingredient: levonorgestrel 1.5 mg

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

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.

Distributed by:

Sun Pharmaceutical Industries, Inc.

Cranbury, NJ 08512

Manufactured by:

Sun Pharmaceutical Industries Limited

Halol-Baroda Highway,

Halol-389 350, Gujarat, India.

ISS. 01/2023

5238568

PRINCIPAL DISPLAY PANEL

See New Warning

NDC 62756-718-60

Opcicon™ One-Step

(Levonorgestrel) Tablet

1.5 mg

Emergency Contraceptive

Reduces chance of pregnancy after unprotected sex.

Not for regular birth control.

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

One Tablet.

One Step.

1 Tablet Levonorgestrel 1.5 mg

See New Warning

NDC 62756-718-60

Opcicon™ One-Step (Levonorgestrel) Tablet

1.5 mg

Emergency Contraceptive

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One Tablet.
One Step.

1 Tablet Levonorgestrel 1.5 mg

Emergency Contraceptive
One Tablet.
One Step.

Opcicon™ One-Step
(Levonorgestrel) Tablet
1.5 mg

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Opcicon™ One-Step
(Levonorgestrel) Tablet
1.5 mg



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ISS: 01/2023

Opcicon™ One-Step
(Levonorgestrel) Tablet
1.5 mg

Emergency Contraceptive
One Tablet.
One Step.

Drug Facts	Levonorgestrel, USP 1.5 mg.....Emergency contraceptive
Active ingredient	
Purpose	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
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 tear strip is removed or blister seal is broken or missing • store at 20° to 25°C (68° to 77°F)
Inactive ingredients	lactose monohydrate, magnesium stearate, talc
Questions or comments?	For more information, call toll free 1-800-818-4555 weekdays
Drug Facts (continued)	When using this product you may have • menstrual changes • dizziness • nausea • headache • breast pain • lower stomach (abdominal) pain • vomiting Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.



Manufactured by:
Sun Pharmaceutical Ind. Ltd.
Halol-Baroda Highway,
Halol-389 350, Gujarat, India.

Distributed by:
Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512

Emergency Contraceptive
One Tablet.
One Step.

OPCICON ONE-STEP
levonorgestrel tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62756-718
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)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	WHITE (white to off-white)	Score	no score
Shape	ROUND (circular)	Size	8mm
Flavor		Imprint Code	718
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62756-718-60	1 in 1 CARTON	09/12/2014	
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	ANDA202635	09/12/2014	

Labeler - Sun Pharmaceutical Industries, Inc. (146974886)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Limited		725959238	ANALYSIS(62756-718) , MANUFACTURE(62756-718)

Revised: 1/2023

Sun Pharmaceutical Industries, Inc.