

**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**
- 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 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 is one tablet with levonorgestrel, a hormone that has been used in many birth control pills for several decades. Opcicon™ One-Step 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 Opcicon™ One-Step 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 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. 09/2017

PJPI0313B

### **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

Reduces the 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



1 Tablet Levonorgestrel 1.5 mg

One Tablet.  
One Step.

Emergency Contraceptive  
One Tablet.  
One Step.

Opcicon™ One-Step  
(Levonorgestrel) Tablet  
1.5 mg

Opcicon™ One-Step  
(Levonorgestrel) Tablet  
1.5 mg



PJSB0738D  
GUJ/DRUGS/28/396

PJSB0738D

ISS: 09/2017

Opcicon™ One-Step  
(Levonorgestrel) Tablet  
1.5 mg

Emergency Contraceptive  
One Tablet.  
One Step.

<b>Drug Facts</b>	<b>Drug Facts</b> (continued)
<b>Active ingredient</b> Levonorgestrel, USP 1.5 mg.....Emergency contraceptive	
<b>Purpose</b> Use for women to reduce chance of pregnancy after unprotected sex (if a contraceptive failed or if you did not use birth control)	
<b>Warnings</b> <b>Allergy alert:</b> Do not use if you have ever had an allergic reaction to levonorgestrel <b>Sexually transmitted diseases (STDs) alert:</b> This product does not protect against HIV/AIDS or other STDs.	
<b>Do not use</b> • if you are already pregnant (because it will not work) • for regular birth control	
<b>Ask a doctor or pharmacist before use if you are taking efavirenz (HIV medication) or rifampin (tuberculosis treatment) or medication for seizures (epilepsy).</b> These medications may reduce the effectiveness of levonorgestrel.	
<b>When using this product you may have</b> • menstrual changes • tiredness • dizziness • nausea • headache • breast pain • lower stomach (abdominal) pain • vomiting	
<b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.	
<b>Other information</b> • 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 20° to 25°C (68° to 77°F)	<b>Questions or comments?</b> For more information, call toll free 1-800-818-4555 weekdays
<b>Directions</b> • 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	
	<b>Inactive ingredients</b> colloidal silicon dioxide, corn starch, hypromellose, lactose monohydrate, magnesium stearate, talc



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**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62756-718
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
LEVONORGESTREL (UNII: 5W7SIA7YZW) (LEVONORGESTREL - UNII:5W7SIA7YZW)	LEVONORGESTREL	1.5 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TALC (UNII: 7SEV7J4R1U)	

**Product Characteristics**

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

**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**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA202635	09/12/2014	

**Labeler** - Sun Pharmaceutical Industries, Inc. (146974886)**Establishment**

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