LEVONORGESTREL- levonorgestrel tablet
NuCare Pharmaceuticals,Inc.

Take Action ®

Drug Facts

Active ingredient

Levonorgestrel 1.5mg

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

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 20-25°C (68-77°F)

Inactive ingredients

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

Questions?

Call **1-866-626-6990**

CONSUMER INFORMATION

take action®

LEVONORGESTREL 1.5mg

Emergency Contraceptive

One Tablet. One Dose.

Teva Women's Health, Inc.

What is Take Action ®?

Take Action ® 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 Take Action ® is not.

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

When should I use Take Action ®?

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

Take Action ® 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 Take Action ®?

Take Action ® 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 Take Action ®

How does Take Action ® work?

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

You have 72 hours (3 days) to try to prevent pregnancy after unprotected sex. **The sooner you take Take Action ®, the better it works** .

How effective is Take Action ®?

If Take Action ® 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 if Take Action ® worked?

You will know Take Action ® 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, Take Action ® 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 Take Action ®?

If you have questions or need more information, call our toll-free number, 1-866-626-6990.

Other information

Keep out of reach of children:

In case of overdose, get medical help or contact the 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 (68-77°F).
You may report side effects to FDA at 1-800-FDA-1088.

Active ingredient: levonorgestrel 1.5 mg

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

1-866-626-6990

If you are sexually active, you should see a healthcare provider for routine

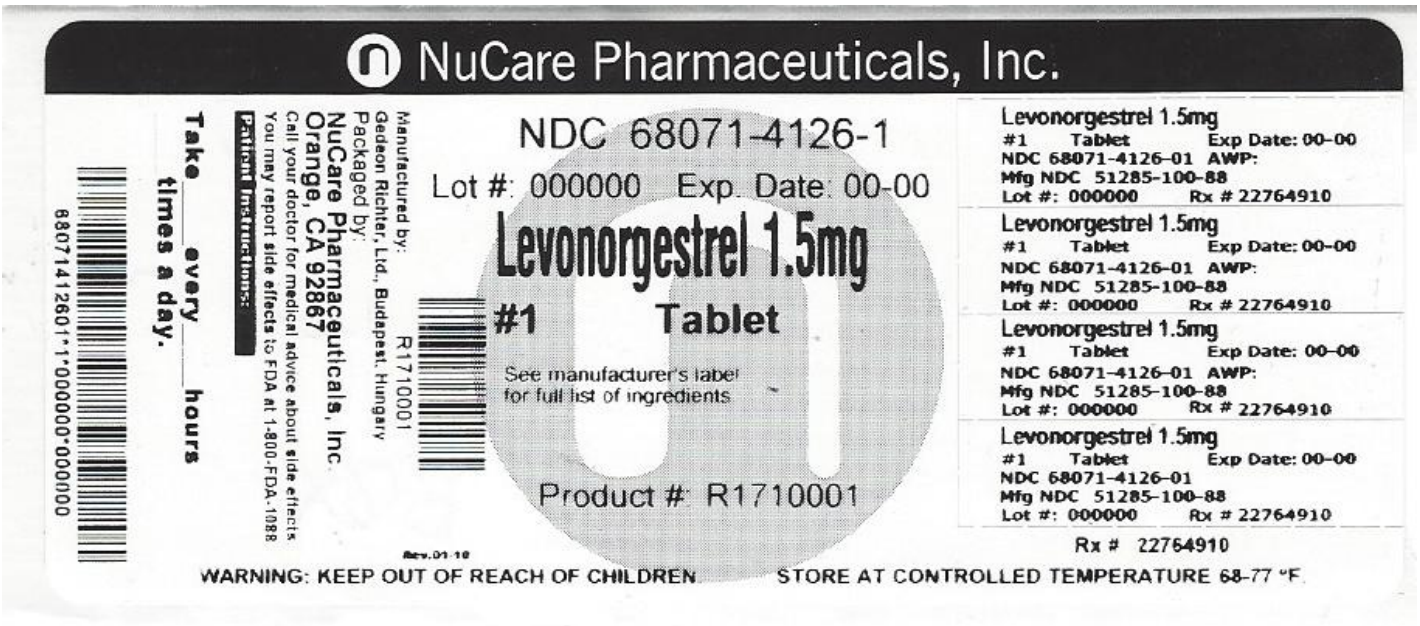
checkups. Your healthcare provider will talk to you about, and if necessary, test you for sexually transmitted diseases, teach you about effective methods of routine birth control, and answer any other questions you may have.

take action®

LEVONORGESTREL 1.5mg

Rev. 11/2014

Principal Display Panel



LEVONORGESTREL

levonorgestrel tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68071-4126(NDC:51285-100)

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)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, POTATO (UNII: 8I089SAH3T)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics			
Color	white	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	G00
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68071-4126-1	1 in 1 BOX; Type 0: Not a Combination Product	10/25/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA021998	02/17/2014	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-4126)