

**NEW DAY- levonorgestrel tablet**  
**Northstar Rx LLC**

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**New Day™ (Levonorgestrel Tablet, 1.5mg)**

**Drug Facts**

**ACTIVE INGREDIENT**

Levonorgestrel 1.5mg

**PURPOSE**

Emergency contraception

**USE**

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**

**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 blister seal is broken or missing.
- Store at 20° to 25°C (68° to 77°F).

## INACTIVE INGREDIENT

magnesium stearate, lactose monohydrate, pregelatinized starch, polyvinyl alcohol, titanium dioxide, talc, macrogol/PEG, lecithin (soya), FD&C red#40 aluminum lake, FD&C yellow#6 aluminum lake, FD&C blue#1 aluminum lake.

## QUESTIONS

For more information or to speak to a healthcare professional, call: 1-800-206-7821

### New Day™

**(levonorgestrel Tablet), 1.5 mg**

**Emergency Contraceptive**

**One Tablet. One Dose.**

### **What is New Day™? What You Need to Know**

New Day™ 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 New Day™ is not.**

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

### **When should I use New Day™?**

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

New Day™ 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 New Day™.**

New Day™ 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 New Day™.

### **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 New Day™ 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 New Day™ work?**

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

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

### **How effective is New Day™?**

If New Day™ 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 New Day™ worked?**

You will know New Day™ 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, New Day™ 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 New Day™?**

If you have questions or need more information, call our toll-free number, 1-800-206-7821.

### **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:** magnesium stearate, lactose monohydrate, pregelatinized starch, polyvinyl alcohol, titanium dioxide, talc, macrogol/PEG, lecithin (soya), FD&C red#40 aluminum lake, FD&C yellow#6 aluminum lake, FD&C blue#1 aluminum lake.

**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: Northstar Rx LLC  
Memphis, TN 38141

Manufactured by: Novast Laboratories Ltd.  
Nantong, China 226009

10052  
Rev. A  
Iss. 03/2018

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**



## NEW DAY

levonorgestrel tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:16714-809
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
MAGNESIUM STEARATE (UNII: 70097M6I30)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

### Product Characteristics

<b>Color</b>	PINK	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	15
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16714-809-01	1 in 1 CARTON	03/11/2016	
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	ANDA207976	03/11/2016	

**Labeler** - Northstar Rx LLC (830546433)

**Registrant** - Novast Laboratories, Ltd. (527695995)

### Establishment

Name	Address	ID/FEI	Business Operations
Novast Laboratories, Ltd.		527695995	analysis(16714-809) , label(16714-809) , manufacture(16714-809) , pack(16714-809)

Revised: 4/2018

Northstar Rx LLC