

NEW DAY- levonorgestrel tablet
Northstar Rx LLC

New Day® (Levonorgestrel Tablet, 1.5mg)

Drug Facts

Active Ingredient

Levonorgestrel 1.5mg

Purpose

Emergency Contraceptive

Use

Use for women to reduce the 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 blister seal is broken or missing.**
- store at 20° to 25°C (68° to 77°F).

Inactive ingredients

lactose monohydrate, magnesium stearate, 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 or comments?

For more information or to speak to a healthcare professional, call: **1-800-206-7821**. (Monday to Friday 9:00am to 7:00pm EST)

New Day

(Levonorgestrel Tablet) 1.5 mg

emergency contraceptive

One Tablet. One Dose.

What you need to know

1 Blister Card with 1 Tablet.

What is New Day®?

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® works before release of an egg from the ovary. As a result, New Day® usually stops or delays the release of an egg from the ovary. New Day® 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 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.

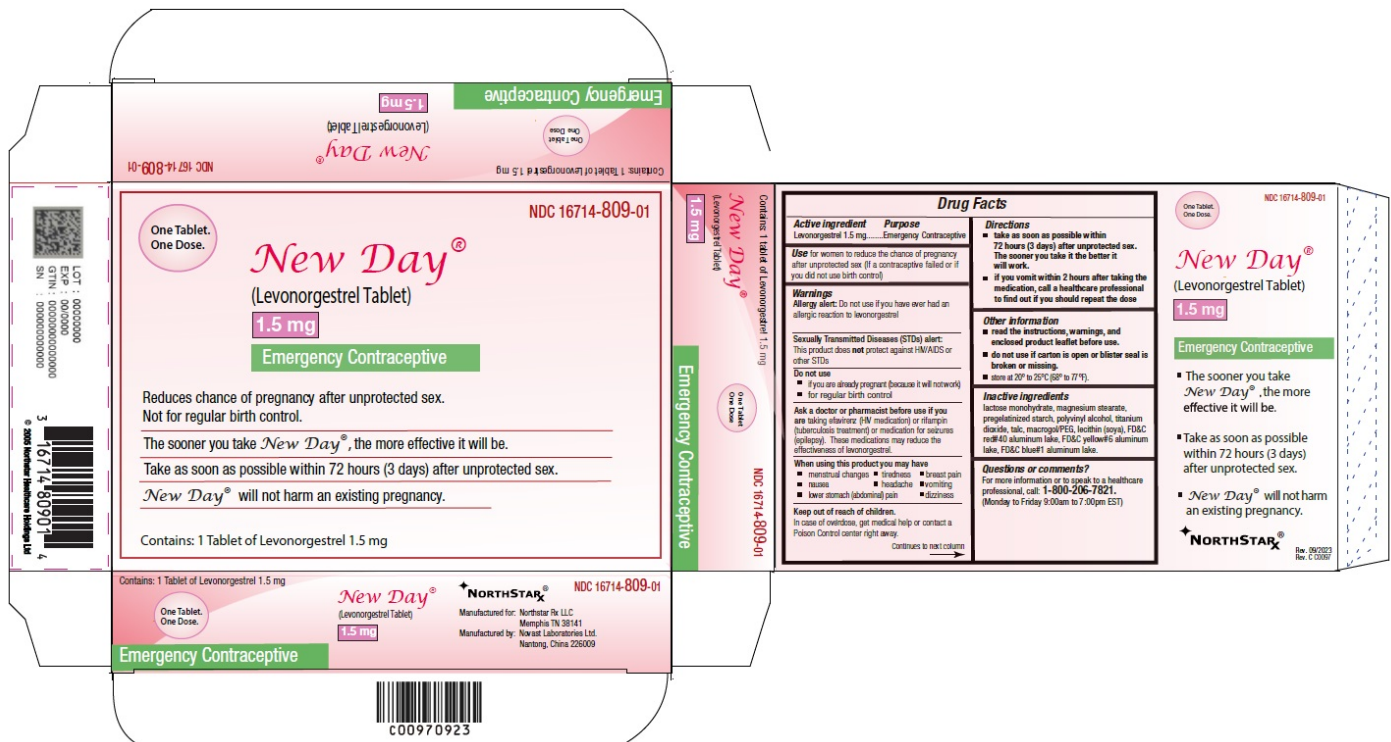
NORTHSTAR[®]

New Day[®]

Manufactured for: Northstar Rx LLC
Memphis, TN 38141

Manufactured by: Novast Laboratories Ltd.
Nantong, China 226009

10052
Rev. B
Rev. 09/2023



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: 5W7SIA7YZ W) (LEVONORGESTREL - UNII:5W7SIA7YZ W)		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 GLYCOL 3350 (UNII: G2M7P15E5P)				
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				
Color	PINK	Score	no score	
Shape	ROUND	Size	8mm	
Flavor		Imprint Code	15	
Contains				
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,		527695995	analysis(16714-809) , label(16714-809) , manufacture(16714-809) ,

Revised: 10/2023

Northstar Rx LLC