

ECONTRA EZ- levonorgestrel tablet
Afaxys Inc.

EContra® EZ
(Levonorgestrel) Tablet, 1.5 mg

Emergency Contraceptive

One Tablet Equals One Dose.

What You Need to Know

What is EContra EZ?

EContra EZ 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 EContra EZ is not.

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

When should I use EContra EZ?

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

EContra EZ 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 EContra EZ.

EContra EZ 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 EContra EZ.

How does EContra EZ work?

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

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

How effective is EContra EZ?

If EContra EZ 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 EContra EZ worked?

You will know EContra EZ 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, EContra EZ 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 EContra EZ?

If you experience side effects while taking EContra EZ you may report them to the Afaxys Health and Safety team at **1-855-888-2467** or to FDA at **1-800-FDA 1088**.

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, corn starch, lactose monohydrate, magnesium stearate, povidone K-25.

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.

afaxys[®]

Manufactured for:

Afaxys, Inc.

Charleston, SC, 29403, USA.

Manufactured by:

Jai Pharma Ltd., India

200010574-003

REVISED: AUGUST 2016



Recyclable Paper

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 50102-111-01

EMERGENCY CONTRACEPTION

EContra[®] EZ

(Levonorgestrel) Tablet, 1.5 mg

One Tablets Equals One Dose.

Reduces chance of pregnancy after unprotected sex.

The sooner you take it, the more effective it will be

Take as soon as possible within 72 hours (3 days)

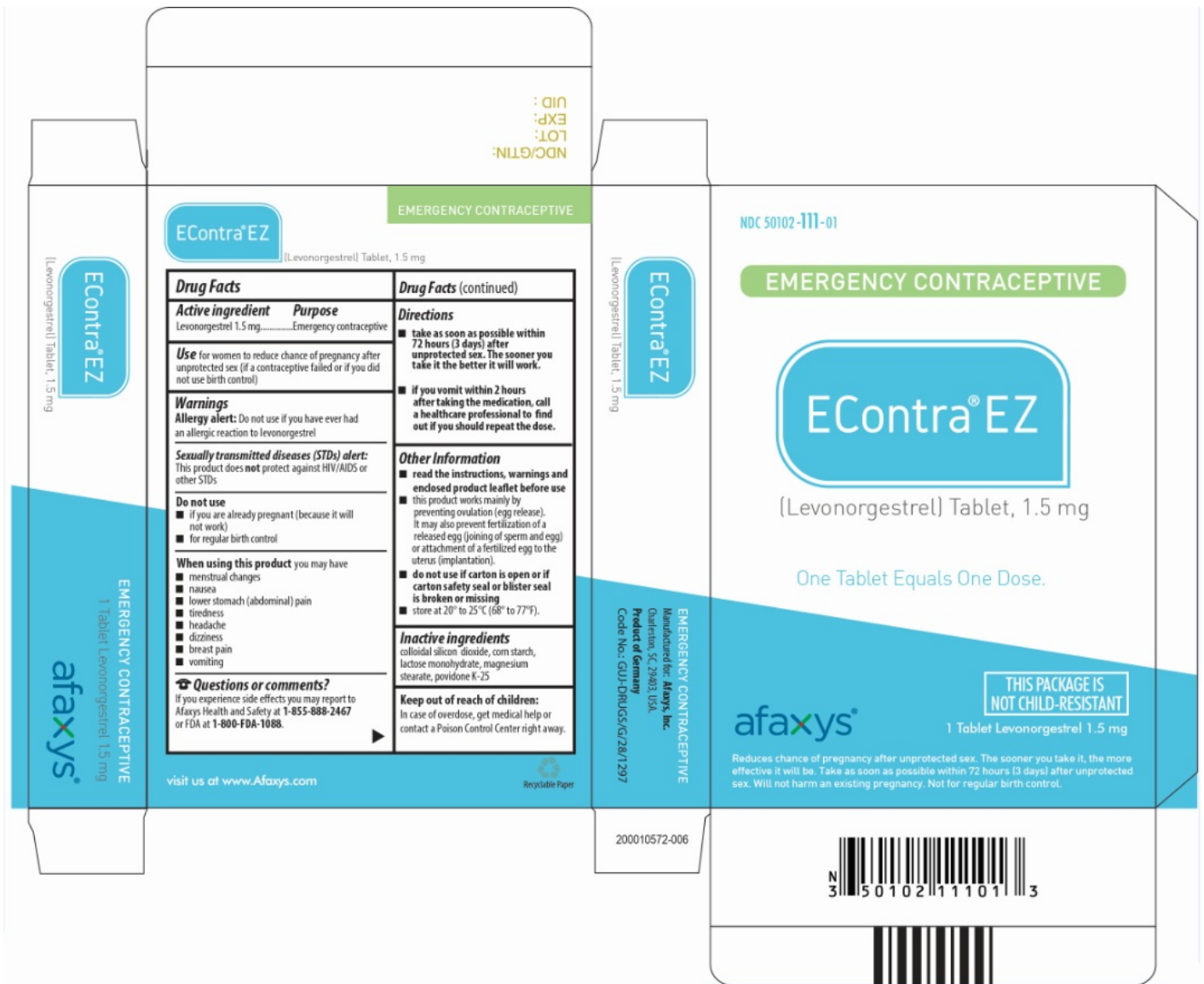
after unprotected sex

Will not harm an existing pregnancy

Not for regular birth control.

THIS PACKAGE IS NOT CHILD-RESISTANT

1 Tablet Levonorgestrel 1.5 mg



ECONTRA EZ

levonorgestrel tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50 102-111
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)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE K25 (UNII: K0KQV10C35)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	WHITE (white to off-white)	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	251
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50 102-111-12	12 in 1 PACKAGE	01/01/2015	
1	NDC:50 102-111-01	1 in 1 CARTON		
1	NDC:50 102-111-00	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	ANDA202739	01/01/2015	

Labeler - Afaxys Inc. (832701960)

Registrant - Jai Pharma Limited (650882132)

Establishment			
Name	Address	ID/FEI	Business Operations
Jai Pharma Limited		677604150	analysis(50 102-111) , manufacture(50 102-111) , pack(50 102-111) , label(50 102-111)