

ECONTRA EZ - levonorgestrel tablet
Afaxys Pharma, LLC

EContra[®] EZ
(Levonorgestrel) Tablet, 1.5 mg

Emergency Contraceptive

One Tablet. 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.

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 EContra[®] EZ 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 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 have questions or need more information, call **1-855-888-2467** or go to www.afaxys.com, 24 hours a day/7 days a week or FDA at **1-800-FDA-1088** or www.fda.gov/medwatch

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 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 Pharma LLC.

Charleston, SC, 29403, USA.

Manufactured by:

Mylan Laboratories Limited

200012782-000

REVISED: JANUARY 2018



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)

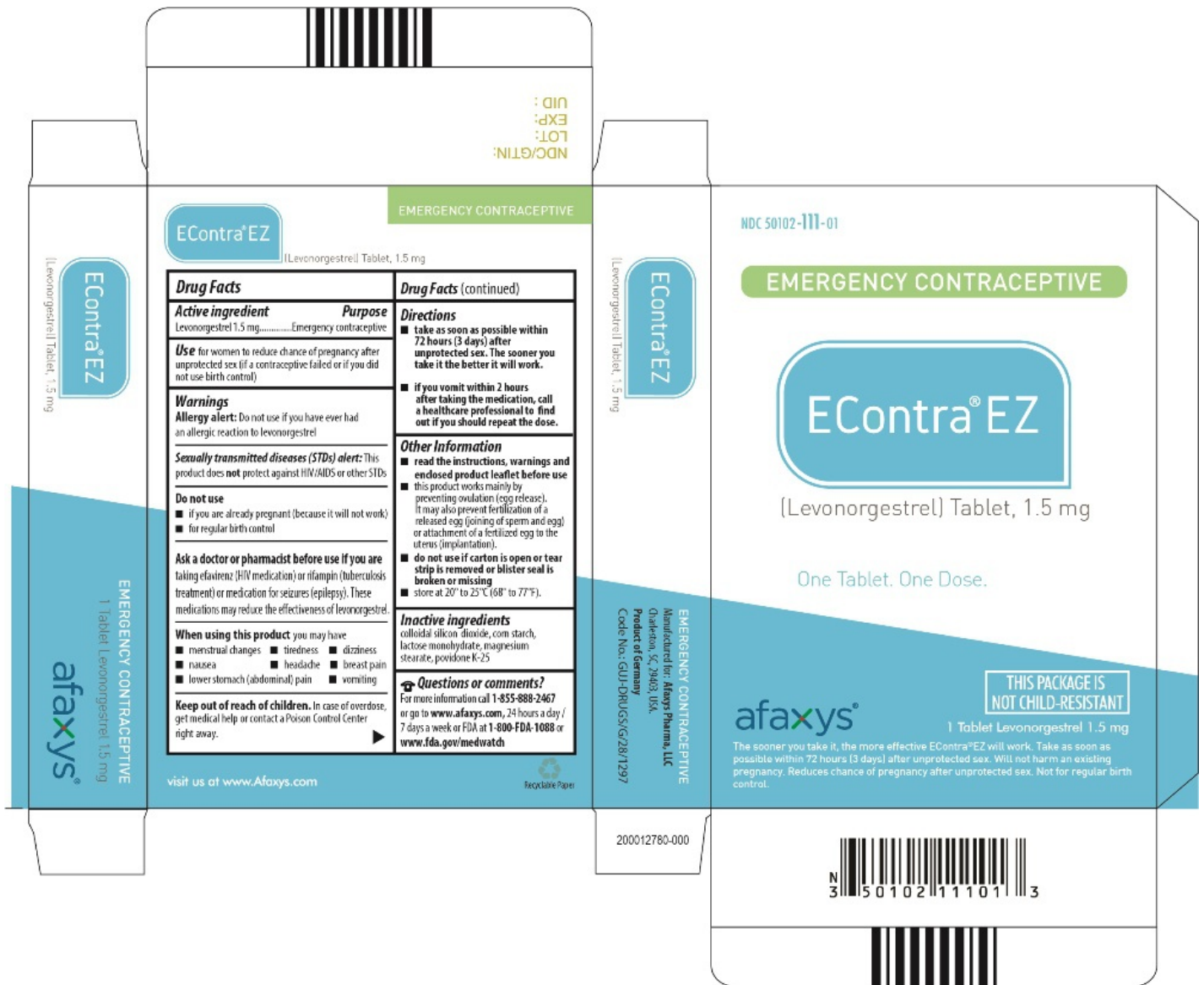
after unprotected sex

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: EWQ57Q815X) | |

| | |
|--|--|
| 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 Pharma, LLC (080508656)

Registrant - Mylan Laboratories Limited (650547156)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|---------|-----------|---|
| Mylan Laboratories Limited | | 677604150 | analysis(50 102-111) , manufacture(50 102-111) , pack(50 102-111) , label(50 102-111) |

Revised: 1/2020

Afaxys Pharma, LLC