

ECONTRA ONE-STEP - levonorgestrel tablet
Afaxys Pharma, LLC

EContra One-Step®
(Levonorgestrel) Tablet 1.5 mg

Drug Facts

Active ingredient (in each tablet)

Levonorgestrel 1.5 mg

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

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 (1-800-222-1222) 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 seal is removed**
- store at 20° to 25°C (68° to 77°F)

Inactive ingredients

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

Questions?

Call **1-855-888-2467**

Manufactured for:

Afaxys Pharma, LLC

Charleston, SC, 29403, USA

Manufactured by:

Aurobindo Pharma Limited

Unit-VII (SEZ)

Mahabubnagar (Dt)-509302, India

Made in India

Code: TS/DRUGS/22/2009

Patient Information

EContra One-Step[®] **(Levonorgestrel) Tablet, 1.5 mg** **Emergency Contraceptive** **One Tablet. One Step.** **What You Need to Know**

What is EContra One-Step[®]?

EContra One-Step[®] 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 One-Step[®] is not.

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

When should I use EContra One-Step[®]?

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

EContra One-Step[®] 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 One-Step[®].

EContra One-Step[®] 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 One-Step[®].

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 One-Step[®] 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 One-Step[®] work?

EContra One-Step[®] works before release of an egg from the ovary. As a result, EContra One-Step[®] usually stops or delays the release of an egg from the ovary. EContra One-Step[®] 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 EContra One-Step[®]?

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

How effective is EContra One-Step[®]?

If EContra One-Step[®] 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 One-Step[®] worked?

You will know EContra One-Step[®] 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 One-Step[®] 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 One-Step[®]?

If you have questions or need more information, call our toll-free number Afaxys Pharma, LLC at 1-855-888-2467.

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, potato starch, and talc.

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.

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Revised: 03/2023

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1.5 mg (3 Blister Carton Label)

**†Compares to the active ingredient of Plan B One-Step®
NDC 50102-211-13**

EMERGENCY CONTRACEPTIVE

EContra One-Step®

(Levonorgestrel) Tablet, 1.5 mg

Reduces chance of pregnancy after unprotected sex.

Not for regular birth control.

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.

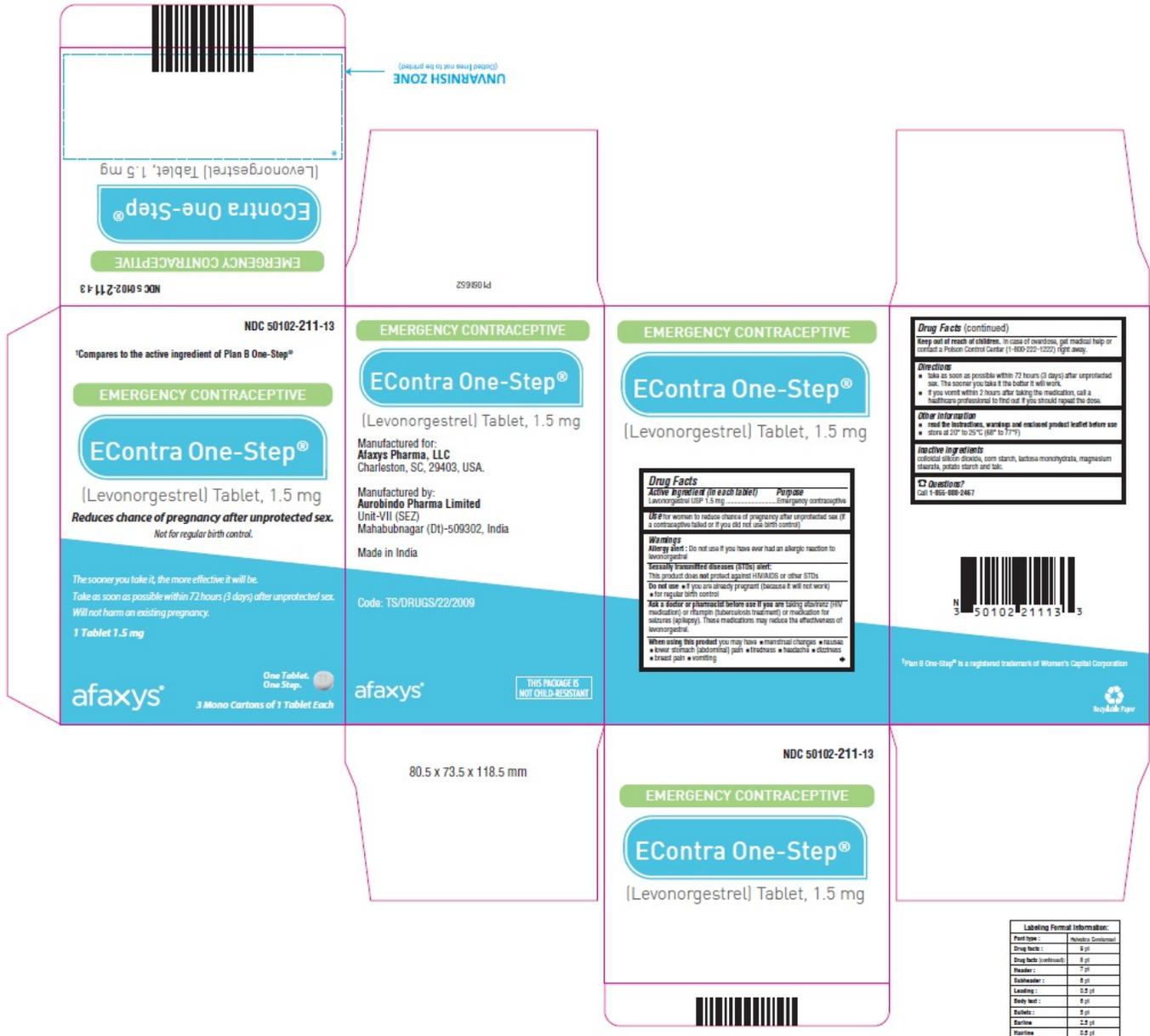
1 Tablet 1.5 mg

One Tablet.

One Step.

afaxys®

3 Mono Cartons of 1 Tablet Each



| Labeling Format Information: | |
|------------------------------|------------------|
| Field Name | Selected Content |
| Drug Facts | 0 pt |
| Directions | 0 pt |
| Warnings | 0 pt |
| Instructions | 0 pt |
| Labeling | 0.5 pt |
| Other | 0 pt |
| Tablets | 0 pt |
| Tablets | 0.5 pt |
| Tablets | 0.5 pt |

ECONTRA ONE-STEP

levonorgestrel tablet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50102-211 |
| 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 | | |
| 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 (White to off-white) | Score | no score | |
| Shape | ROUND | Size | 8mm | |
| Flavor | | Imprint Code | S;11 | |
| Contains | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:50102-211-16 | 6 in 1 PACKAGE | 02/08/2018 | 08/31/2022 |
| 1 | NDC:50102-211-11 | 1 in 1 CARTON | | |
| 1 | NDC:50102-211-01 | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:50102-211-13 | 3 in 1 PACKAGE | 10/27/2020 | |
| 2 | NDC:50102-211-11 | 1 in 1 CARTON | | |
| 2 | NDC:50102-211-01 | 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 | ANDA206867 | 02/08/2018 | | |

Labeler - Afaxys Pharma, LLC (080508656)

Registrant - Aurobindo Pharma Limited (650082092)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|--|
| Aurobindo Pharma Limited | | 650381903 | ANALYSIS(50102-211) , MANUFACTURE(50102-211) |

Revised: 4/2023

Afaxys Pharma, LLC