

EContra One-Step®

(levonorgestrel) tablet, 1.5 mg

Over-the-Counter

afaxys®
pharma

**ECONTRA ONE-STEP® IS AN OVER-THE-COUNTER
EMERGENCY CONTRACEPTIVE THAT IS
COMPARABLE TO PLAN B ONE-STEP®**

**OTHER 1.5 MG LEVONORGESTREL EMERGENCY
CONTRACEPTIVE PRODUCTS INCLUDE:**

Aftera®, AfterPill®, EContra® EZ, My Way®,
Opcicon™ One-Step, and Take Action®



- A levonorgestrel emergency contraceptive
 - Levonorgestrel tablet should be taken within 72 hours (3 days) after unprotected sex or a known contraceptive failure
 - Single-tablet dosing

Packaging Description	NDC #	Dimensions
A Box Containing 3 Monocartons	50102-211-13	80.5 mm x 73.5 mm x 118.5 mm (3pk)

SEE ALL ORDERING INFORMATION

ADDITIONAL PRODUCT INFORMATION¹:

- EContra One-Step works for up to 72 hours (3 days) after unprotected sex or contraceptive failure
- Offers convenient, single-tablet dosing
- Following administration of EContra One-Step, your patients may resume or initiate their chosen method of contraception immediately – no waiting required²

Side effects may include changes in period, nausea, abdominal pain, tiredness, headache, dizziness, and breast tenderness. EContra One-Step does not protect against HIV/AIDS or other sexually transmitted diseases (STDs).

Please see Important Safety Information below.

EContra One-Step[®]

(levonorgestrel) tablet, 1.5 mg

Over-the-Counter

Please see accompanying
full Product Information

PRODUCT INFORMATION for EContra One-Step[®] (levonorgestrel tablet, 1.5mg)¹

INDICATIONS

EContra One-Step is a progestin-only emergency contraceptive pill for use in women to reduce the chance of pregnancy after unprotected sex (if contraceptive failed or birth control not used). EContra One-Step is not intended to be used in place of routine birth control.

Consult the Package Insert or [click here](#) for Drug Label Information

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.
- **Pregnancy alert**—Do not use if you are already pregnant (because it will not work).
- **Interaction with other medications**—Women should ask a doctor or pharmacist before using EContra One-Step if taking efavirenz (HIV medication) or rifampin (tuberculosis treatment) or medication for seizures (epilepsy). These medications may reduce the effectiveness of levonorgestrel.

ADVERSE REACTIONS

Commonly reported adverse reactions include menstrual changes, abdominal pain, nausea, vomiting, tiredness, headache, dizziness, or breast pain.

References: 1. EContra One-Step product information, Charleston, SC, USA: Afaxys Pharma, LLC; September 2020.
2. World Health Organization. Fact sheets: emergency contraception. November 9, 2021. Accessed August 19, 2022. <https://www.who.int/news-room/fact-sheets/detail/emergency-contraception>

To report **SUSPECTED ADVERSE REACTIONS**, call 1-855-888-2467 or report via the FDA MedWatch Program at www.fda.gov/medwatch or 1-800-FDA-1088.

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

One-Step® 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 One-Step® 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 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.

Manufactured for:

Afaxys Pharma, LLC

Charleston, SC, 29403, USA.

Made in India

Code: TS/DRUGS/22/2009

Revised: 11/2019

P1522818

