

TAKE ACTION- levonorgestrel tablet
Teva Women's Health, Inc.

Take Action®

Drug Facts

Active ingredient

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 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**
- this product works mainly by preventing ovulation (egg release). It may also prevent fertilization of a released egg (joining of sperm and egg) or attachment of a fertilized egg to the uterus (implantation).
- **do not use if carton is open or tear strip is removed or blister seal is broken or missing.**
- store at 20-25°C (68-77°F)

Inactive ingredients

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

Questions?

Call 1-866-626-6990

CONSUMER INFORMATION

take
action[®]

LEVONORGESTREL 1.5mg

**Emergency Contraceptive
One Tablet. One Dose.**

Teva Women's Health, Inc.

What is TAKE ACTION[®]?

TAKE ACTION 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 TAKE ACTION is not.

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

When should I use TAKE ACTION?

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

TAKE ACTION 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 TAKE ACTION?

TAKE ACTION 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 TAKE ACTION

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 TAKE ACTION 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 TAKE ACTION work?

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

You have 72 hours (3 days) to try to prevent pregnancy after unprotected sex. **The sooner you take TAKE ACTION, the better it works.**

How effective is TAKE ACTION?

If TAKE ACTION 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 if TAKE ACTION worked?

You will know TAKE ACTION 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 periods, 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, TAKE ACTION 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 medication, call a healthcare professional to find out if you should repeat the dose.

What if I still have questions about TAKE ACTION?

If you have questions or need more information, call our toll-free number, 1-866-626-6990.

Other information

Keep out of reach of children:

In case of overdose, get medical help or contact the Poison Control Center right away at 1-800-222-1222.

Do not use if the blister seal is opened.

Store at room temperature 20-25°C (68-77°F).

You may report side effects to FDA at 1-800-FDA-1088.

Active ingredient: levonorgestrel 1.5 mg

Inactive ingredients: colloidal silicon dioxide, potato starch, magnesium stearate, talc, corn starch, lactose monohydrate

1-866-626-6990

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.

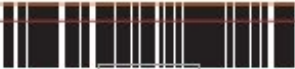
take
action[®]
LEVONORGESTREL 1.5mg

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Rev. 9/2017

Principal Display Panel, Part 1 of 3



Principal Display Panel, Part 2 of 3



799-30-101168 Rev. 9/2017

Emergency Contraceptive

Emergency Contraceptive
One Tablet, One Dose.

take
action[®]

LEVONORGESTREL 0.02 mg

take
action[®]

LEVONORGESTREL 0.02 mg

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.

Drug Facts

| Active ingredient | Purpose |
|-----------------------|-------------------------|
| Levonorgestrel 1.5 mg | 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: (if medication) or change (subacute treatment) or medication for seizure (epilepsy). These medications may reduce the effectiveness of levonorgestrel.
When using this product you may have:
 • menstrual changes • dizziness • breast pain
 • nausea • headache • vomiting
 • lower stomach (abdominal) pain • diarrhea


Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control center right away.

Directions:
 • Take one dose 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 this medication, call a doctor or pharmacist for more information.
 • Do not take more than one dose.

Other information:
 • Read the instructions, warnings and enclosed product leaflet before use.
 • This product works mostly by preventing ovulation (egg release).
 • It does not work if you are already pregnant or if you are taking it after you have become pregnant.
 • Do not use if the tablet is open or has a chip or removed or if the seal is broken.
 • NDA 201-022 (09-17-17)

Inactive ingredients: colloidal silicon dioxide, corn starch, lactose monohydrate, magnesium stearate, polydextrose, talc.

Questions? Call 1-866-625-6228



51285-100-88 N

Principal Display Panel, Part 3 of 3



Take Action® (levonorgestrel 1.5 mg) 1s Unit-Dose Box Text

NDC 51285-100-88

Emergency Contraceptive

See New Warning

take

action®

LEVONORGESTREL 1.5mg

Reduces chance of pregnancy
after unprotected sex.

NOT FOR REGULAR BIRTH CONTROL

One Tablet.

One Dose.

1 Tablet

Levonorgestrel

1.5 mg

TAKE ACTION

levonorgestrel tablet

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:51285-100 |
| 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) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| STARCH, POTATO (UNII: 8I089SAH3T) | |
| TALC (UNII: 7SEV7J4R1U) | |

Product Characteristics

| | | | |
|----------|-------|--------------|----------|
| Color | WHITE | Score | no score |
| Shape | ROUND | Size | 8mm |
| Flavor | | Imprint Code | G00 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:51285-100-88 | 1 in 1 BOX, UNIT-DOSE | 02/17/2014 | 12/31/2020 |
| 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 |
|------------------------|--|----------------------|--------------------|
| NDA AUTHORIZED GENERIC | NDA021998 | 02/17/2014 | 12/31/2020 |

