



CONSUMER INFORMATION

Next Choice™ (levonorgestrel) Tablets, 0.75 mg

Emergency Contraceptive

Contains FD&C yellow #6 as a color additive.

Next Choice™ Emergency Contraceptive.

Important Information About Next Choice™, Birth Control & Sexually Transmitted Diseases.

For additional information intended for healthcare professionals, please see enclosed Product Information for Next Choice™.



What is Next Choice™?

Next Choice™ is emergency contraception that helps prevent pregnancy after birth control failure or unprotected sex. It is a **backup** method of preventing pregnancy and is not to be used routinely.

Next Choice™ can reduce your chance of pregnancy after unprotected sex (if your regular birth control was used incorrectly or fails, or if you have had sex without birth control). For example, if you were using a condom and it broke or slipped, if you did not use your regular birth control as you should have, or if you did not use any birth control, Next Choice™ may work for you.

What Next Choice™ is not.

Next Choice™ will not work if you are already pregnant and will not affect an existing pregnancy. Next Choice™ should not be used as regular birth control. It is important to have another reliable source of birth control that is right for you. Next Choice™ will not protect you from HIV infection (the virus that causes AIDS) and other sexually transmitted diseases.

When is the appropriate time to use Next Choice™?

You can use Next Choice™ **after** you have had unprotected sex in the last 72 hours (3 days), and you do not want to become pregnant.

Next Choice™ can be used as a backup or emergency method to regular birth control if, for example,

- Your regular birth control method was used incorrectly or failed (your partner's condom broke or slipped)
- You made a mistake with your regular method
- You did not use any birth control method

When is it not appropriate to use Next Choice™?

- Next Choice™ should not be used as a regular birth control method. It does not work as well as most other forms of birth control when they are used consistently and correctly. Next Choice™ is a backup or emergency method of contraception.
- Next Choice™ should not be used if you are already pregnant because it will not work.
- Next Choice™ should not be used if you are allergic to levonorgestrel or any other ingredients in Next Choice™.
- Next Choice™ does not protect against HIV (the virus that causes AIDS) or other sexually transmitted diseases (STDs). The best ways to protect yourself against getting HIV or other STDs are to use a latex condom correctly with every sexual act or not to have sex at all.

How does Next Choice™ work?

Next Choice™ is two pills with levonorgestrel, a hormone that has been used in many birth control pills for over 35 years. Next Choice™ 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 Next Choice™ 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 Next Choice™?

You have only a few days to try to prevent pregnancy after unprotected sex. **The sooner you take Next Choice™, the better it will work.** Take the first Next Choice™ tablet **as soon as possible within 72 hours (3 days)** after unprotected sex. Take the second tablet **12 hours** later.

How effective is Next Choice™?

The sooner you take Next Choice™, the better it will work. Take Next Choice™ as soon as possible after unprotected sex. If it is taken as soon as possible within 72 hours (3 days) after unprotected sex, it will significantly decrease the chance that you will get pregnant. Seven out of every 8 women who would have gotten pregnant will not become pregnant.

How will I know if Next Choice™ worked?

Most women will have their next menstrual period at the expected time or within a week of the expected time. If your menstrual period is delayed beyond 1 week, you may be pregnant. You should get a pregnancy test and follow up with your healthcare professional.

What if I am already pregnant and use Next Choice™?

There is no medical evidence that Next Choice™ would harm a developing baby. If you take Next Choice™ (accidentally) after you are already pregnant or it does not work and you become pregnant, it is not likely to cause any harm to you or your pregnancy. The pregnancy will continue. Next Choice™ will not work if you are already pregnant.

What should I do if my menstrual period is delayed beyond 1 week and I have severe lower stomach (abdominal) pain?

No. Next Choice™ should not be used for emergency protection only, and is not designed to be used frequently. If you find that you need to use emergency contraception often, talk to your healthcare professional and learn about methods of birth control and STD prevention that are right for you.

Can I use Next Choice™ for regular birth control?

When used as directed, Next Choice™ is safe for women. Some women will have mild, temporary side effects, such as menstrual changes, nausea, lower stomach (abdominal) pain, tiredness, headache, dizziness, breast pain and vomiting. These are similar to the side effects that some women have when taking regular birth control pills. Some women taking Next Choice™ will have menstrual changes such as spotting or bleeding before their next period. Some women may have a heavier or lighter next period, or a period that is early or late. **If your period is more than a week late, you should get a pregnancy test.**

How often can I use Next Choice™?

Next Choice™ should not be used for regular birth control. It is an emergency or backup method to be used if your regular birth control fails or is used incorrectly or if you have sex without birth control. You should protect yourself against STDs and pregnancy every time you have sex. If you have unprotected sex again after taking Next Choice™, it will not help protect you from getting pregnant.

Will I experience any side effects from Next Choice™?

Next Choice™ is meant for emergency protection only, and is not designed to be used frequently. If you find that you need to use emergency contraception often, talk to your healthcare professional and learn about methods of birth control and STD prevention that are right for you.

What warnings should I know about when using Next Choice™?

Next Choice™ does not protect against the AIDS virus (HIV) or other sexually transmitted diseases (STDs).

Do not use:

- If you are already pregnant (because it will not work)
- If you are allergic to levonorgestrel or any of the ingredients in Next Choice™
- For regular birth control

When using this product, you may have:

- Menstrual changes
- Tiredness
- Breast pain
- Nausea
- Headache
- Vomiting
- Lower stomach (abdominal) pain
- Dizziness

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.

What are the directions for using Next Choice™?**Women 17 years of age and older:**

- Take the first Next Choice™ tablet as soon as possible within 72 hours (3 days) after unprotected sex.
- Take the second tablet 12 hours after you take the first tablet.
- If you vomit within 2 hours of taking either dose of medication, call a healthcare professional to find out if you should repeat that dose.

Prescription only for women younger than age 17. If you are younger than 17, see a healthcare professional.

What should I do if I have questions about Next Choice™?

If you have questions or need more information about this product, call our toll-free number, 1-866-9WATSON (1-866-992-8766), visit our website at www.mynextchoice.com, or ask a healthcare professional.

Other information

This package is sealed for your protection. **Do not use if torn or broken.**

Store at 20° to 25°C (68° to 77°F) [see USP controlled room temperature].

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Active ingredient: levonorgestrel 0.75 mg in each tablet

Inactive ingredients: colloidal silicon dioxide, povidone, magnesium stearate, FD&C yellow #6, corn starch, lactose monohydrate

Protect yourself in more ways than one!

If you are sexually active, but you are not ready for a pregnancy, it is important to use regular pregnancy protection. There are many types of birth control. Whichever type you choose, it is important to use your regular birth control method as directed. This ensures that you have effective protection against pregnancy every time you have sex.

But things do not always go as planned. For example, if you were using a condom and it broke or slipped, or if you did not use your regular birth control as you should have, or if you did not use any birth control, Next Choice™ may work for you. Next Choice™ is an emergency contraceptive that helps prevent pregnancy after unprotected sex or when your birth control fails or is not used correctly.

Remember, Next Choice™ is only for emergency pregnancy prevention. There are many other products that work for regular birth control that are available by prescription or over-the-counter.

There is also another form of protection to think about when you have sex: protection against sexually transmitted diseases (STDs). Some common STDs are HIV/AIDS, chlamydia, genital herpes, gonorrhea, hepatitis, human papilloma virus (HPV), genital warts, syphilis, and trichomonas. Some of these STDs can be very serious and can lead to infertility (inability to have a baby), problems during pregnancy, chronic illness, and even death.

All sexually active women are at risk of catching STDs because they may not know that their partner has an STD (the partner himself may not know). **If your partner uses a latex condom correctly each and every time you have sex with him, this will help reduce, but not eliminate, the chance that you will catch an STD.**

No other birth control methods will effectively protect you from STDs. The female condom may give you some STD protection, but it is not as effective as a male latex condom.

For more information on STDs, call the Centers for Disease Control and Prevention (CDC) AIDS/STD Hotline. The CDC phone numbers are 1-800-342-AIDS (2437) for English, 1-800-344-7432 for Spanish, or 1-800-243-7889 for hearing impaired, TDD.

Be sure to protect yourself against pregnancy and STDs by using some form of birth control plus a latex condom. Of course, not having sex is the most effective way to prevent pregnancy and stay free of STDs.

Next Choice™ is used to prevent pregnancy after unprotected sex.

Next Choice™ should not be used for regular birth control, if you are already pregnant (because it will not work), or if you are allergic to levonorgestrel or any of the ingredients in Next Choice™.

The sooner you take Next Choice™, the better it will work.

Next Choice™ does not protect against the AIDS virus (HIV) or other sexually transmitted diseases (STDs)

Common side effects associated with the use of Next Choice™ include menstrual changes, nausea, lower stomach (abdominal) pain, tiredness, headache, dizziness, breast pain and vomiting.

Phone: 1-866-9WATSON (1-866-992-8766)

www.mynextchoice.com

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Revised: November 2009
1109B

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