# LEVONORGESTREL EMERGENCY CONTRACEPTIVE- levonorges trel tablet Perrigo New York Inc

-----

#### HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Levonorgestrel tablets, 0.75 mg safely and effectively. See full prescribing information for Levonorgestrel tablets, 0.75 mg.

Levonorgestrel Tablets, 0.75 mg, for oral use

Initial U.S. Approval: 1982
INDICATIONS AND USAGE
Levonorgestrel tablets, 0.75 mg is a progestin-only emergency contraceptive, indicated for prevention of pregnancy following unprotected intercourse or a known or suspected contraceptive failure. Levonorgestrel tablets, 0.75 mg is available only by prescription for women younger than age 17 years, and available over the counter for women 17 years and older. Levonorgestrel tablets, 0.75 mg is not intended for routine use as a contraceptive. (1)
DOSAGE AND ADMINIST RATION
The first tablet is taken orally <u>as soon as possible within 72 hours</u> after unprotected intercourse. The second tablet should be taken 12 hours after the first dose. Efficacy is better if Levonorgestrel tablets, 0.75 mg is taken as soon as possible after unprotected intercourse. (2)
DOSAGE FORMS AND STRENGTHS
A total of two 0.75 mg tablets taken 12 hours apart as a single course of treatment. (3)CONTRAINDICATIONS
Known or suspected pregnancy. (4)
WARNINGS AND PRECAUTIONS

- Ectopic Pregnancy: Women who become pregnant or complain of lower abdominal pain after taking Levonorgestrel tablets, 0.75 mg should be evaluated for ectopic pregnancy. (5.1)
- Levonorgestrel tablets, 0.75 mg is not effective in terminating an existing pregnancy. (5.2)
- Effect on menses: Levonorgestrel tablets, 0.75 mg may alter the next expected menses. If menses is delayed beyond 1 week, pregnancy should be considered. (5.3)
- STI/HIV: Levonorgestrel tablets, 0.75 mg does not protect against STI/HIV. (5.4)

------ ADVERSE REACTIONS ------

The most common adverse reactions (> 10%) in the clinical trial included menstrual changes (26%), nausea (23%), abdominal pain (18%), fatigue (17%), headache (17%), dizziness (11%), and breast tenderness (11%). (6.1) To report SUSPECTED ADVERSE REACTIONS, contact Call 1-800-719-9260, or contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

----- DRUG INTERACTIONS ·····

Drugs or herbal products that induce certain enzymes, such as CYP3A4, may decrease the effectiveness of progestin-only pills. (7)

------USE IN SPECIFIC POPULATIONS ------

- Nursing Mothers: Small amounts of progestin pass into the breast milk of nursing women taking progestin-only pills for long-term contraception, resulting in detectable steroid levels in infant plasma. (8.3)
- Levonorgestrel tablets, 0.75 mg is not intended for use in premenarcheal (8.4) or postmenopausal females. (8.5)
- Clinical trials demonstrated a higher pregnancy rate in the Chinese population. (8.6)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 1/2014

#### **3 DOSAGE FORMS AND STRENGTHS**

#### **4 CONTRAINDICATIONS**

#### **5 WARNINGS AND PRECAUTIONS**

- 5.1 Ectopic Pregnancy
- 5.2 Existing Pregnancy
- 5.3 Effects on Menses
- 5.4 STI/HIV
- 5.5 Physical Examination and Follow-Up
- 5.6 Fertility Following Discontinuation

# **6 ADVERSE REACTIONS**

- 6.1 Clinical Trial Experience
- 6.2 Postmarketing Experience

#### 7 DRUG INTERACTIONS

#### **8 USE IN SPECIFIC POPULATIONS**

- 8.1 Pregnancy
- 8.3 Nursing Mothers
- 8.4 Pediatric Use
- 8.5 Geriatric Use
- 8.6 Race
- 8.7 Hepatic Impairment
- 8.8 Renal Impairment

#### 9 DRUG ABUSE AND DEPENDENCE

- **10 OVERDOSAGE**
- 11 DESCRIPTION

#### 12 CLINICAL PHARMACOLOGY

- 12.1 Mechanism of Action
- 12.3 Pharmacokinetics

#### 13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

- 14 CLINICAL STUDIES
- 16 HOW SUPPLIED/STORAGE AND HANDLING

#### 17 PATIENT COUNSELING INFORMATION

17.1 Information for Patients

#### **FULL PRESCRIBING INFORMATION**

#### 1 INDICATIONS AND USAGE

Levonorgestrel tablets, 0.75 mg is a progestin-only emergency contraceptive indicated for prevention of pregnancy following unprotected intercourse or a known or suspected contraceptive failure. To obtain optimal efficacy, the first tablet should be taken as soon as possible within 72 hours of intercourse. The second tablet should be taken 12 hours later.

Levonorgestrel tablets, 0.75 mg is available only by prescription for women younger than age 17 years, and available over the counter for women 17 years and older.

Levonorgestrel tablets, 0.75 mg is not indicated for routine use as a contraceptive.

#### 2 DOSAGE AND ADMINISTRATION

<sup>\*</sup> Sections or subsections omitted from the full prescribing information are not listed.

Take one tablet of Levonorgestrel tablets, 0.75 mg orally <u>as soon as possible within 72 hours</u> after unprotected intercourse or a known or suspected contraceptive failure. Efficacy is better if the tablet is taken as soon as possible after unprotected intercourse. The second tablet should be taken 12 hours after the first dose. Levonorgestrel tablets, 0.75 mg can be used at any time during the menstrual cycle.

If vomiting occurs within two hours of taking either dose of medication, consideration should be given to repeating the dose.

#### **3 DOSAGE FORMS AND STRENGTHS**

Each Levonorgestrel tablets, 0.75 mg tablet is supplied as a white to off-white circular, flat beveled, uncoated tablet debossed with "L840" on one side and plain on the other side.

#### **4 CONTRAINDICATIONS**

Levonorgestrel tablets, 0.75 mg is contraindicated for use in the case of known or suspected pregnancy.

#### **5 WARNINGS AND PRECAUTIONS**

# **5.1 Ectopic Pregnancy**

Ectopic pregnancies account for approximately 2% of all reported pregnancies. Up to 10% of pregnancies reported in clinical studies of routine use of progestin-only contraceptives are ectopic.

A history of ectopic pregnancy is not a contraindication to use of this emergency contraceptive method. Healthcare providers, however, should consider the possibility of an ectopic pregnancy in women who become pregnant or complain of lower abdominal pain after taking Levonorgestrel tablets, 0.75 mg. A follow-up physical or pelvic examination is recommended if there is any doubt concerning the general health or pregnancy status of any woman after taking Levonorgestrel tablets, 0.75 mg.

#### 5.2 Existing Pregnancy

Levonorgestrel tablets, 0.75 mg is not effective in terminating an existing pregnancy.

#### 5.3 Effects on Menses

Some women may experience spotting a few days after taking Levonorgestrel tablets, 0.75 mg. Menstrual bleeding patterns are often irregular among women using progestin-only oral contraceptives and women using levonorgestrel for postcoital and emergency contraception.

If there is a delay in the onset of expected menses beyond 1 week, consider the possibility of pregnancy.

#### **5.4 STI/HIV**

Levonorgestrel tablets, 0.75 mg does not protect against HIV infection (AIDS) or other sexually transmitted infections (STIs).

## 5.5 Physical Examination and Follow-Up

A physical examination is not required prior to prescribing Levonorgestrel tablets, 0.75 mg. A follow-up physical or pelvic examination is recommended if there is any doubt concerning the general health or pregnancy status of any woman after taking Levonorgestrel tablets, 0.75 mg.

# 5.6 Fertility Following Discontinuation

A rapid return of fertility is likely following treatment with Levonorgestrel tablets, 0.75 mg for emergency contraception; therefore, routine contraception should be continued or initiated as soon as

possible following use of Levonorgestrel tablets, 0.75 mg to ensure ongoing prevention of pregnancy.

#### **6 ADVERSE REACTIONS**

# 6.1 Clinical Trial Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

A double-blind, controlled clinical trial in 1,955 evaluable women compared the efficacy and safety of levonorgestrel tablets, 0.75 mg (one 0.75 mg tablet of levonorgestrel taken within 72 hours of unprotected intercourse, and one tablet taken 12 hours later) to the Yuzpe regimen (two tablets each containing 0.25 mg levonorgestrel and 0.05 mg ethinyl estradiol, taken within 72 hours of intercourse, and two tablets taken 12 hours later).

The most common adverse events (> 10%) in the clinical trial for women receiving levonorgestrel tablets, 0.75 mg included menstrual changes (26%), nausea (23%), abdominal pain (18%), fatigue (17%), headache (17%), dizziness (11%), and breast tenderness (11%). Table 1 lists those adverse events that were reported in  $\geq$  5% of levonorgestrel tablets, 0.75 mg users.

**Table 1: Adverse Events in ≥ 5% of Women, by % Frequency** 

	levonorges trel tablets, 0.75 mg N=977 (%)
Nausea	23.1
Abdominal Pain	17.6
Fatigue	16.9
Headache	16.8
Heavier Menstrual Bleeding	13.8
Lighter Menstrual Bleeding	12.5
Dizziness	11.2
Breast Tenderness	10.7
Vomiting	5.6
Diarrhea	5.0

# **6.2 Postmarketing Experience**

The following adverse reactions have been identified during post-approval use of levonorgestrel tablets, 0.75 mg. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Gastrointestinal Disorders

Abdominal Pain, Nausea, Vomiting

General Disorders and Administration Site Conditions

Fatigue

*Nervous System Disorders* 

Dizziness, Headache

Reproductive System and Breast Disorders

Dysmenorrhea, Irregular Menstruation, Oligomenorrhea, Pelvic Pain

#### 7 DRUG INTERACTIONS

Drugs or herbal products that induce enzymes, including CYP3A4, that metabolize progestins may decrease the plasma concentrations of progestins, and may decrease the effectiveness of progestin-only pills. Some drugs or herbal products that may decrease the effectiveness of progestin-only pills include:

- barbiturates
- bosentan
- carbamazepine
- felbamate
- griseofulvin
- oxcarbazepine
- phenytoin
- rifampin
- St. John's wort
- topiramate

Significant changes (increase or decrease) in the plasma levels of the progestin have been noted in some cases of co-administration with HIV protease inhibitors or with non-nucleoside transcriptase inhibitors.

Consult the labeling of all concurrently used drugs to obtain further information about interactions with progestin-only pills or the potential for enzyme alterations.

#### **8 USE IN SPECIFIC POPULATIONS**

# 8.1 Pregnancy

Many studies have found no harmful effects on fetal development associated with long-term use of contraceptive doses of oral progestins. The few studies of infant growth and development that have been conducted with progestin-only pills have not demonstrated significant adverse effects.

## 8.3 Nursing Mothers

In general, no adverse effects of progestin-only pills have been found on breastfeeding performance or on the health, growth or development of the infant. However, isolated post-marketing cases of decreased milk production have been reported. Small amounts of progestins pass into the breast milk of nursing mothers taking progestins-only pills for long-term contraception, resulting in detectable steroid levels in infant plasma.

## 8.4 Pediatric Use

Safety and efficacy of progestin-only pills for long-term contraception have been established in women of reproductive age. Safety and efficacy are expected to be the same for postpubertal adolescents less than 17 years and for users 17 years and older. Use of Levonorgestrel tablets, 0.75 mg emergency contraception before menarche is not indicated.

#### 8.5 Geriatric Use

This product is not intended for use in postmenopausal women.

#### 8.6 Race

No formal studies have evaluated the effect of race. However, clinical trials demonstrated a higher pregnancy rate in Chinese women with both levonorgestrel tablets, 0.75 mg and the Yuzpe regimen (another form of emergency contraception). The reason for this apparent increase in the pregnancy rate with emergency contraceptives in Chinese women is unknown.

# 8.7 Hepatic Impairment

No formal studies were conducted to evaluate the effect of hepatic disease on the disposition of levonorgestrel tablets, 0.75 mg.

# 8.8 Renal Impairment

No formal studies were conducted to evaluate the effect of renal disease on the disposition of levonorgestrel tablets, 0.75 mg.

#### 9 DRUG ABUSE AND DEPENDENCE

Levonorgestrel is not a controlled substance. There is no information about dependence associated with the use of levonorgestrel tablets, 0.75 mg.

#### 10 OVERDOSAGE

There are no data on overdosage of levonorgestrel tablets, 0.75 mg, although the common adverse event of nausea and associated vomiting may be anticipated.

#### 11 DESCRIPTION

Each Levonorgestrel tablet contains 0.75 mg of a single active steroid ingredient, levonorgestrel [18,19-Dinorpregn-4-en-20-yn-3-one-13-ethyl-17-hydroxy-,  $(17\alpha)$ -(-)-], a totally synthetic progestogen. The inactive ingredients present are colloidal silicon dioxide, corn starch, lactose monohydrate, magnesium stearate, and povidone. Levonorgestrel has a molecular weight of 312.45, and the following structural and molecular formulas:

 $C_{21}H_{28}O_2$ 

#### 12 CLINICAL PHARMACOLOGY

# 12.1 Mechanism of Action

Emergency contraceptive pills are not effective if a woman is already pregnant. Levonorgestrel tablets, 0.75 mg is believed to act as an emergency contraceptive principally by preventing ovulation or fertilization (by altering tubal transport of sperm and/or ova). In addition, it may inhibit implantation (by altering the endometrium). It is not effective once the process of implantation has begun.

#### 12.3 Pharmacokinetics

# Absorption

No specific investigation of the absolute bioavailability of levonorgestrel tablets, 0.75 mg in humans has been conducted. However, literature indicates that levonorgestrel is rapidly and completely absorbed after oral administration (bioavailability about 100%) and is not subject to first pass metabolism.

After a single dose of levonorgestrel tablets, 0.75 mg administered to 16 women under fasting conditions, the mean maximum serum concentration of levonorgestrel was 14.1 ng/mL at an average of 1.6 hours. See Table 2.

Table 2: Pharmacokinetic Parameter Values Following Single Dose Administration of Levonorgestrel Tablets, 0.75 mg to Healthy Female Volunteers under Fasting Conditions

	Mean (± SD)					
	$C_{max}(ng/mL)$	$T_{max}$ (h)	CL	$V_d(L)$	t <sub>1/2</sub> (h)	AUC <sub>inf</sub> (ng•hr/mL)
	,		(L/h)		,	
levonorgestrel	14.1 (7.7)	1.6 (0.7)	7.7 (2.7)	260.0	24.4 (5.3)	123.1 (50.1)

 $C_{max} = maximum concentration$ 

 $T_{max}$  = time to maximum concentration

CL = clearance

 $V_d$  = volume of distribution

 $t_{1/2}$  = elimination half life

AUC<sub>inf</sub> = area under the drug concentration curve from time 0 to infinity

Effect of Food: The effect of food on the rate and the extent of levonorgestrel absorption following single oral administration of levonorgestrel tablets, 0.75 mg has not been evaluated.

#### Distribution

The apparent volume of distribution of levonorgestrel is reported to be approximately 1.8 L/kg. It is about 97.5 to 99% protein-bound, principally to sex hormone binding globulin (SHBG) and, to a lesser extent, serum albumin.

#### Metabolism

Following absorption, levonorgestrel is conjugated at the  $17\beta$ -OH position to form sulfate conjugates and, to a lesser extent, glucuronide conjugates in plasma. Significant amounts of conjugated and unconjugated  $3\alpha$ ,  $5\beta$ -tetrahydrolevonorgestrel are also present in plasma, along with much smaller amounts of  $3\alpha$ ,  $5\alpha$ -tetrahydrolevonorgestrel and  $16\beta$ hydroxylevonorgestrel. Levonorgestrel and its phase I metabolites are excreted primarily as glucuronide conjugates. Metabolic clearance rates may differ among individuals by several-fold, and this may account in part for the wide variation observed in levonorgestrel concentrations among users.

#### Excretion

About 45% of levonorgestrel and its metabolites are excreted in the urine and about 32% are excreted in feces, mostly as glucuronide conjugates.

## Specific Populations

Pediatric: This product is not intended for use in the premenarcheal population, and pharmacokinetic data are not available for this population.

Geriatric: This product is not intended for use in postmenopausal women, and pharmacokinetic data are not available for this population.

Race: No formal studies have evaluated the effect of race on pharmacokinetics of levonorgestrel tablets, 0.75 mg. However, clinical trials demonstrated a higher pregnancy rate in Chinese women with

both levonorgestrel tablets, 0.75 mg and the Yuzpe regimen (another form of emergency contraception). The reason for this apparent increase in the pregnancy rate with emergency contraceptives in Chinese women is unknown [see USE IN SPECIFIC POPULATIONS(8.6)].

Hepatic Impairment: No formal studies were conducted to evaluate the effect of hepatic disease on the disposition of levonorgestrel tablets, 0.75 mg.

Renal Impairment: No formal studies were conducted to evaluate the effect of renal disease on the disposition of levonorgestrel tablets, 0.75 mg.

**Drug-Drug Interactions** 

No formal drug-drug interaction studies were conducted with levonorgestrel tablets, 0.75 mg [see *DRUG INTERACTIONS (7)*].

## 13 NONCLINICAL TOXICOLOGY

# 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity: There is no evidence of increased risk of cancer with short-term use of progestins. There was no increase in tumorgenicity following administration of levonorgestrel to rats for 2 years at approximately 5  $\mu$ g/day, to dogs for 7 years at up to 0.125 mg/kg/day, or to rhesus monkeys for 10 years at up to 250  $\mu$ g/kg/day. In another 7 year dog study, administration of levonorgestrel at 0.5 mg/kg/day did increase the number of mammary adenomas in treated dogs compared to controls. There were no malignancies.

Genotoxicity: Levonorgestrel was not found to be mutagenic or genotoxic in the Ames Assay, *in vitro* mammalian culture assays utilizing mouse lymphoma cells and Chinese hamster ovary cells, and in an *in vivo* micronucleus assay in mice.

Fertility: There are no irreversible effects on fertility following cessation of exposures to levonorgestrel or progestins in general.

#### 14 CLINICAL STUDIES

A double-blind, randomized, multinational controlled clinical trial in 1,955 evaluable women (mean age 27) compared the efficacy and safety of levonorgestrel tablets, 0.75 mg (one 0.75 mg tablet of levonorgestrel taken within 72 hours of unprotected intercourse, and one tablet taken 12 hours later) to the Yuzpe regimen (two tablets each containing 0.25 mg levonorgestrel and 0.05 mg ethinyl estradiol, taken within 72 hours of intercourse, and two additional tablets taken 12 hours later). After a single act of intercourse occurring anytime during the menstrual cycle, the expected pregnancy rate of 8% (with no contraceptive use) was reduced to approximately 1% with levonorgestrel tablets, 0.75 mg.

Emergency contraceptives are not as effective as routine hormonal contraception since their failure rate, while low based on a single use, would accumulate over time with repeated use [see INDICATIONS AND USAGE (1)].

At the time of expected menses, approximately 74% of women using levonorgestrel tablets, 0.75 mg had vaginal bleeding similar to their normal menses, 14% bled more than usual, and 12% bled less than usual. The majority of women (87%) had their next menstrual period at the expected time or within +7 days, while 13% had a delay of more than 7 days beyond the anticipated onset of menses.

# 16 HOW SUPPLIED/STORAGE AND HANDLING

Levonorgestrel tablets, 0.75 mg are available for a single course of treatment in PVC/aluminum foil blister packages of two tablets each. The tablet is white to off-white, circular, flat beveled, uncoated tablet debossed with "L840" on one side and plain on the other side.

Available as: Unit-of-use NDC 45802-840-54

Store Levonorgestrel tablets, 0.75 mg at controlled room temperature, 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [See USP].

#### 17 PATIENT COUNSELING INFORMATION

#### 17.1 Information for Patients

- Take Levonorgestrel tablets, 0.75 mg as soon as possible and not more than 72 hours after unprotected intercourse or a known or suspected contraceptive failure.
- If you vomit within two hours of taking either tablet, immediately contact your healthcare provider to discuss whether to take another tablet.
- Seek medical attention if you experience severe lower abdominal pain 3 to 5 weeks after taking Levonorgestrel tablets, 0.75 mg, in order to be evaluated for an ectopic pregnancy.
- After taking Levonorgestrel tablets, 0.75 mg, consider the possibility of pregnancy if your period is delayed more than one week beyond the date you expected your period.
- Do not use Levonorgestrel tablets, 0.75 mg as routine contraception.
- Levonorgestrel tablets, 0.75 mg is not effective in terminating an existing pregnancy.
- Levonorgestrel tablets, 0.75 mg does not protect against HIV-infection (AIDS) and other sexually transmitted diseases/infections.
- For women younger than age 17 years, Levonorgestrel tablets, 0.75 mg is available only by prescription.

Phone: **1-800-719-9260** Website: www.Levo4U.com

Product Made in India **DISTRIBUTED BY** 

PERRIGO® ALLEGAN, MI 49010

Rev 10/09

# **Patient Package Insert**

Levonorges trel Tablets, 0.75 mg Emergency Contraceptive Protect Yourself & Your Future

Important Information AboutLevonorgestrel Tablets, 0.75 mg, Birth Control & Sexually Transmitted Diseases

For additional information intended for healthcare professionals, please see enclosed Product Information for Levonorgestrel tablets, 0.75 mg.

## What is Levonorgestrel tablets, 0.75 mg?

Levonorgestrel tablets, 0.75 mg 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.

Levonorgestrel tablets, 0.75 mg 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, Levonorgestrel tablets, 0.75 mg may work for you.

# What Levonorgestrel tablets, 0.75 mg is not.

Levonorgestrel tablets, 0.75 mg will not work if you are already pregnant and will not affect an existing pregnancy. Levonorgestrel tablets, 0.75 mg should not be used as regular birth control. It is important to haveanother reliable source of birth control that is right for you. Levonorgestrel tablets, 0.75 mg will not protect you from HIV infection (the virus that causes AIDS) and other sexually transmitted diseases.

# When is the appropriate time to use Levonorgestrel tablets, 0.75 mg?

You can use Levonorgestrel tablets, 0.75 mg **after** you have had unprotected sex in the last 72 hours (3 days), and you do not want to become pregnant.

Levonorgestrel tablets, 0.75 mg 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 Levonorgestrel tablets, 0.75 mg?

- Levonorgestrel tablets, 0.75 mg 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. Levonorgestrel tablets, 0.75 mg is a <u>backup or emergency</u> method of contraception.
- Levonorgestrel tablets, 0.75 mg should not be used if you are already pregnant because it will not work.
- Levonorgestrel tablets, 0.75 mg should not be used if you are allergic to levonorgestrel or any other ingredients in Levonorgestrel tablets, 0.75 mg.
- Levonorgestrel tablets, 0.75 mg 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 Levonorgestrel tablets, 0.75 mg work?

Levonorgestrel tablets, 0.75 mg is two pills with levonorgestrel, a hormone that has been used in many birth control pills for over 35 years. Levonorgestrel tablets, 0.75 mg 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 Levonorgestrel tablets, 0.75 mg 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 Levonorgestrel tablets, 0.75 mg?

You have only a few days to try to prevent pregnancy after unprotected sex. **The sooner you take Levonorgestrel tablets, 0.75 mg, the better it works.** Take the first Levonorgestrel tablet, 0.75 mg **as soon as possible within 72 hours (3 days)** after unprotected sex. Take the second tablet **12 hours** later.

# How effective is Levonorgestrel tablets, 0.75 mg?

The sooner you take Levonorgestrel tablets, 0.75 mg, the better it will work. Take Levonorgestrel

tablets, 0.75 mg 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 Levonorgestrel tablets, 0.75 mg 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 Levonorgestrel tablets, 0.75 mg?

There is no medical evidence that Levonorgestrel tablets, 0.75 mg would harm a developing baby. If you take Levonorgestrel tablets, 0.75 mg (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. Levonorgestrel tablets, 0.75 mg 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?

If you have severe lower stomach (abdominal) pain about 3 to 5 weeks after taking Levonorgestrel tablets, 0.75 mg, you may have a pregnancy outside the uterus, which is called a tubal pregnancy. A tubal pregnancy requires immediate medical treatment, so you should see a healthcare professional right away.

# Can I use Levonorgestrel tablets, 0.75 mg for regular birth control?

No. Levonorgestrel tablets, 0.75 mg should <u>not</u> 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 Levonorgestrel tablets, 0.75 mg, it will not help protect you from getting pregnant.

# How often can I use Levonorges trel tablets, 0.75 mg?

Levonorgestrel tablets, 0.75 mg 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.

# Will I experience any side effects from Levonorgestrel tablets, 0.75 mg?

When used as directed, Levonorgestrel tablets, 0.75 mg 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 Levonorgestrel tablets, 0.75 mg 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.** 

What warnings should I know about when using Levonorgestrel tablets, 0.75 mg?

Levonorgestrel tablets, 0.75 mg 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 Levonorgestrel tablets, 0.75 mg
- For regular birth control

# When using this product, you may have:

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

# 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 Levonorgestrel tablets, 0.75 mg?

# Women 17 years of age and older:

- Take the first Levonorgestrel 0.75 mg 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 Levonorgestrel tablets, 0.75 mg?

If you have questions or need more information about this product, call our toll-free number, 1-800-719-9260, visit our website at **www.Levo4U.com**, or ask a healthcare professional.

#### Other information

Tablets are enclosed in a blister seal. **Do not use if the blister seal is broken.** 

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 0.75 mg in each tablet

**Inactive ingredients**: colloidal silicon dioxide, corn starch, lactose monohydrate, magnesium stearate, povidone

# 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, Levonorgestrel tablets, 0.75 mg may work for you. Levonorgestrel tablets, 0.75 mg is an emergency contraceptive that helps prevent pregnancy after unprotected sex or when your birth control fails or is not used correctly.

Remember, Levonorgestrel tablets, 0.75 mg 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.

Levonorgestrel tablets, 0.75 mg is used to prevent pregnancy after unprotected sex.

Levonorgestrel tablets, 0.75 mg 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 Levonorgestrel tablets, 0.75 mg.

The sooner you take Levonorgestrel tablets, 0.75 mg, the better it will work.

Levonorges trel tablets, 0.75 mg does not protect against the AIDS virus (HIV) or other sexually transmitted diseases (STDs)

Common side effects associated with the use of Levonorgestrel tablets, 0.75 mg include menstrual changes, nausea, lower stomach (abdominal) pain, tiredness, headache, dizziness, breast pain and vomiting.

Levonorgestrel Tablets, 0.75 mg

www.Levo4U.com

1-800-719-9260

Product Made in India

MANUFACTURED BY CIPLA LTD.,

MUMBAI, INDIA

DISTRIBUTED BY PERRIGO®

ALLEGAN, MI 49010

March 2011

84000 00 IC2

#### PRINCIPAL DISPLAY PANEL

Compare to Plan  $B {\mathbb R}$  active ingredient

Levonorgestrel Tablets, 0.75 mg

Rx only for women younger than age 17

**Emergency Contraceptive** 

Reduces the chance of pregnancy after unprotected sex (if a regular birth control method fails or after sex without birth control).

Not for regular birth control

Tablet 1

Tablet 2

Take the first tablet as soon as possible within 72 hours (3 days) after unprotected sex. The sooner you take the first tablet, the better Levonorgestrel tablets, 0.75 mg will work. Take the second tablet 12 hours later.

2 Levonorgestrel Tablets 0.75 mg each



Fev. 03/11

ALLEGAN, MI 49010 DISTRIBUTED BY

AIGNI, IABMUM CIPLA LTD., **WANUFACTURED BY** Product Made in India

VISIT OUR WEDSILE SE WWW. LEVO4U.COM. ( Ouestions or comments? Call 1-800-719-9260.

colloidal silicon dioxide, corn starch, lactose monohydrate, magnesium stearate, povidone Inactive ingredients

blister seal is broken. ■ store at 20-25°C (68-77°F)

■ tablets are enclosed in a blister seal. Do not use if the

virus that causes AIDS. See condom labeling for additional STD information. condoms greatly reduce, but do not eliminate, the risk of pregnancy and the risk of catching or spreading HIV, the ■ when used correctly every time you have sex, latex

edd (ojujud of sperm and edg) or attachment of a fertilized edg (foining of sperm and edg) or attachment of a fertilized (eðð í lejeseð) frusk slao breverring ovulstion this broduct works mainly by breventing ovulstion methods used correctly.

this product is not recommended for regular birth control.
 It does not work as well as most other birth control.

■ before using this product read the enclosed consumer information leaflet for complete directions and information leaflet for complete directions and Other information

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

Drug Facts (continued)

call a healthcare professional to find out if you should repeat that dose

- if you vornit within 2 hours of taking the medication,
- take the second tablet 12 hours after you take the 72 hours (3 days) after unprotected sex. The sooner you take the first tablet, the better it will work. ■ take the first tablet as soon as possible within
  - women 17 years of age or older:

Directions

(1-888-222-1222) uu eqicsi µejb or confact a Polson Confrol Center right away. Keep out of reach of children. In case of overdose, get

■ lower stomach (abdominal) pain ■ dizziness ■ реадасле

e tiredness When using this product you may have

■ if you are already pregnant (because it will not work)
■ for regular birth control

ques not protect against HIV/AIDS or other STDs Sexually transmitted diseases (STDs) alert: This product

reaction to levonorgestrel

Allergy alert. Do not use if you have ever had an allergic

**Use** reduces chance of pregnancy after unprotected sex (if a contraceptive falled or if you did not use birth control)

Active ingredient (in each tablet)
Levonorgestrel 0.75mg..........Emetgency contraceptive

Drug Facts

2 Levonorgestrel Tablets 0.75 mg each

# Emergency Contraceptive



■ breast pain

NDC 45802-840-54

Levonorgestrel Tablets 0.75mg

Compare to Plan B® active ingredient

Rx only for women younger than age 17

# **Emergency Contraceptive**

Reduces the chance of pregnancy after unprotected sex (if a regular birth control method fails or after sex without birth control). Not for regular birth control.



Take the first tablet as soon as possible within 72 hours (3 days) after unprotected sex The sooner you take the first tablet, the better Levonorgestrel tablets, 0.75 mg will work. Take the second tablet 12 hours later.

evonorgestrel

2 Levonorgestrel Tablets 0.75 mg each



: 84054 RT

2

evonorgestrel
Tablets 0.75 mg

# **Emergency Contraceptive**

2 Levonorgestrel Tablets 0.75 mg each

Levonorgestrel Tablet 0.75mg Carton

# LEVONORGESTREL EMERGENCY CONTRACEPTIVE

levonorgestrel tablet

Emergency Contraceptive

Product Information				
Product Type	HUMAN PRESCRIPTION DRUG LABEL	Item Code (Source)	NDC:45802- 840	
Route of Administration	ORAL	DEA Schedule		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LEVONORGESTREL (LEVONORGESTREL)	LEVONORGESTREL	0.75 mg	

Inactive Ingredients	
Ingredient Name	Strength
SILICON DIO XIDE	
STARCH, CORN	
LACTOSE MONOHYDRATE	
MAGNESIUM STEARATE	
POVIDONES	

Product Characteristics				
Color	WHITE (white to off-white)	Score	no score	
Shape	ROUND (circular, flat, beveled)	Size	6 mm	
Flavor		Imprint Code	L840	
Contains				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:45802-840-54	1 in 1 CARTON				
1		2 in 1 BLISTER PACK				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA090740	03/10/2011		

# Labeler - Perrigo New York Inc (078846912)

Revised: 1/2014 Perrigo New York Inc