MY WAY - levonorgestrel tablet
GAVIS Pharmaceuticals, LLC.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use My Way safely and effectively. See full prescribing information for My Way.

My Way (Levonorgestrel) TABLET for ORAL use.
Initial U.S. Approval: 1982

INDICATIONS AND USAGE

My way is a progestin-only emergency contraceptive indicated for prevention of pregnancy following unprotected intercourse or a known or suspected contraceptive failure. My way is available only by prescription for women younger than age 17 years, and available over the counter for women 17 years and older. My way is not intended for routine use as a contraceptive. (1)

DOSAGE AND ADMINISTRATION

One tablet taken orally as soon as possible within 72 hours after unprotected intercourse. Efficacy is better if the tablet is taken as soon as possible after unprotected intercourse. (2)

DOSAGE FORMS AND STRENGTHS

1.5 mg tablet (3)

CONTRAINDICATIONS

Known or suspected pregnancy (4)

WARNINGS AND PRECAUTIONS

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

ADVERSE REACTIONS

The most common adverse reactions (≥10%) in clinical trials included heavier menstrual bleeding (31%), nausea (14%), lower abdominal pain (13%), fatigue (13%), headache (10%), and dizziness (10%). (6.1)
To report SUSPECTED ADVERSE REACTIONS, contact at or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

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)
- My way is not intended for use in premenarcheal (8.4) or postmenopausal females (8.5).

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 2/2013

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

My Way 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 tablet should be taken as soon as possible within 72 hours of intercourse.

My Way is available only by prescription for women younger than age 17 years, and available over the counter for women 17 years and older. My Way is not indicated for routine use as a contraceptive.

2 DOSAGE AND ADMINISTRATION

Take My Way orally as soon as possible within 72 hours 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. My Way can be used at any time during the menstrual cycle.

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

3 DOSAGE FORMS AND STRENGTHS

The My Way tablet is supplied as a white to off-white, round, flat tablets containing 1.5 mg of levonorgestrel and debossed with “NL 620” on one side and plain on the other side.

4 CONTRAINDICATIONS

My Way 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 My Way. 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 My Way.

5.2 Existing Pregnancy

My Way is not effective in terminating an existing pregnancy.

5.3 Effects on Menses

Some women may experience spotting a few days after taking My Way. 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

My Way 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 My Way. 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 My Way.

5.6 Fertility Following Discontinuation

A rapid return of fertility is likely following treatment with My Way for emergency contraception; therefore, routine contraception should be continued or initiated as soon as possible following use of My Way to ensure ongoing prevention of pregnancy.

6 ADVERSE REACTIONS

6.1 Clinical Trials 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.

My Way was studied in a randomized, double-blinded multicenter clinical trial. In this study, all women

who had received at least one dose of study medication were included in the safety analysis: 1,379 women in the My Way group, and 1,377 women in the Plan B group (2 doses of 0.75 mg levonorgestrel taken 12 hours apart). The mean age of women given My Way was 27 years. The racial demographic of those enrolled was 54% Chinese, 12% Other Asian or Black, and 34% were Caucasian in each treatment group. 1.6% of women in the My Way group and 1.4% in Plan B group were lost to follow-up.

The most common adverse events (>10%) in the clinical trial for women receiving My Way included heavier menstrual bleeding (30.9%), nausea (13.7%), lower abdominal pain (13.3%), fatigue (13.3%), and headache (10.3%). Table 1 lists those adverse events that were reported in > 4% of My Way users.

Table 1. Adverse Events in > 4% of Women, by % Frequency

Most Common Adverse Events (MedDRA)	
Heavier menstrual bleeding	30.9
Nausea	13.7
Lower abdominal pain	13.3
Fatigue	13.3
Headache	10.3
Dizziness	9.6
Breast tenderness	8.2
Delay of menses (> 7 days)	4.5

6.2 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of Plan B (2 doses of 0.75 mg levonorgestrel taken 12 hours apart). 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 certain enzymes, such as CYP3A4, may decrease the effectiveness of progestin-only pills. (7)

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 reverse 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 progestin-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 My Way 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 Plan B and the Yuzpe regimen (another form of emergency contraception). There was a non-statistically significant increased rate of pregnancy among Chinese women in the My Way trial. 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 tablet.

8.8 Renal Impairment

No formal studies were conducted to evaluate the effect of renal disease on the disposition of My Way.

9 DRUG ABUSE AND DEPENDENCE

Levonorgestrel is not a controlled substance. There is no information about dependence associated with the use of My Way.

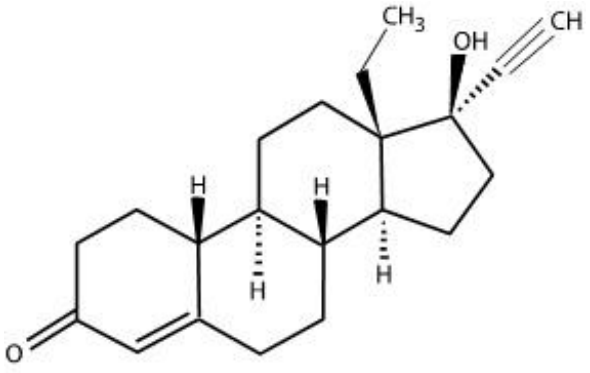
10 OVERDOSAGE

There are no data on overdosage of My Way, although the common adverse event of nausea and associated vomiting may be anticipated.

11 DESCRIPTION

The My Way Tablet contains 1.5 mg of a single active steroid ingredient, levonorgestrel [18,19-Dinorpregn-4-en-20-yn-3-one-13-ethyl-17-hydroxy-, (17α)-(-)-], a totally synthetic progestogen. The inactive ingredients are colloidal silicon dioxide, pregelatinized starch, lactose monohydrate, magnesium stearate, and talc.

Levonorgestrel has a molecular weight of 312.45, and the following structural and molecular formulas:



12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Emergency contraceptive pills are not effective if a woman is already pregnant. My Way 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

Following a single dose administration of My Way in 30 women under fasting conditions, maximum plasma concentrations of levonorgestrel of 19.1 ng/mL were reached at 1.7 hours. See Table 2.

of My Way (levonorgestrel) tablet 1.5 mg to 30 Healthy Female Volunteers under Fasting Conditions[/TC]

Mean (± SD)

	C_{max}(ng/mL)	AUC_t(ng·hr/mL)*	AUC_{inf}(ng·hr/mL)*	T_{max}(hr)**	$t_{1/2}$ (hr)
Levonorgestrel	19.1 (9.7)	294.8(208.8)	307.5(218.5)	1.7(1.0-4.0)	27.5(5.6)

C_{max} = maximum concentration

AUC_t = area under the drug concentration curve from time 0 to time of last determinable concentration

AUC_{inf} = area under the drug concentration curve from time 0 to infinity

T_{max} = time to maximum concentration

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

* N=29

** median (range)

Effect of Food: The effect of food on the rate and the extent of levonorgestrel absorption following single oral administration of My Way 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 17β-OH position to form sulfate conjugates and, to a lesser extent, glucuronide conjugates in plasma. Significant amounts of conjugated and unconjugated 3α, 5β-tetrahydrolevonorgestrel are also present in plasma, along with much smaller amounts of 3α, 5α-tetrahydrolevonorgestrel and 16β-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. However, clinical trials demonstrated a higher pregnancy rate in Chinese women with both Plan B and the Yuzpe regimen (another form of emergency contraception). There was a non-statistically significant increased rate of pregnancy among Chinese women in the My Way trial. 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 My Way.

Renal Impairment

No formal studies were conducted to evaluate the effect of renal disease on the disposition of My Way.

Drug-Drug Interactions

No formal drug-drug interaction studies were conducted with My Way [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 µg/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 µg/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, multicenter, multinational study evaluated and compared the efficacy and safety of three different regimens for emergency contraception. Subjects were enrolled at 15 sites in 10 countries; the racial/ethnic characteristics of the study population overall were 54% Chinese, 34% Caucasian, and 12% Black or Asian (other than Chinese). 2,381 healthy women with a mean age of 27 years, who needed emergency contraception within 72 hours of unprotected intercourse were involved and randomly allocated into one of the two levonorgestrel groups. A single dose of 1.5 mg of levonorgestrel (My Way) was administered to women allocated into group 1. Two doses of 0.75 mg levonorgestrel 12 hours apart (Plan B) were administered to women in group 2. In the My Way group, 16 pregnancies occurred in 1,198 women and in the Plan B group, 20 pregnancies occurred in 1,183 women. The number of pregnancies expected in each group was calculated based on the timing of intercourse with regard to each woman's menstrual cycle. Among women receiving My Way, 84% of expected pregnancies were prevented and among those women taking Plan B, 79% of expected pregnancies were prevented. The expected pregnancy rate of 8% (with no contraceptive use) was reduced to approximately 1% with My Way.

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

In the clinical study, bleeding disturbances were the most common adverse event reported after taking the levonorgestrel-containing regimens. More than half of the women had menses within two days of the expected time; however, 31% of women experienced change in their bleeding pattern during the study period; 4.5% of women had menses more than 7 days after the expected time.

16 HOW SUPPLIED/STORAGE AND HANDLING

The My Way (Levonorgestrel) tablet , 1.5 mg is available in a PVC/aluminum foil blister package. The tablet is a white to off-white, round, flat tablet debossed with "NL 620" on one side and plain on the other side containing 1.5 mg of levonorgestrel.

NDC 43386-620-30 (1 tablet unit of use package)

Store My Way at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

17 PATIENT COUNSELING INFORMATION

17.1 Information for Patients

- Take My Way 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 the 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 My Way, in order to be evaluated for an ectopic pregnancy.
- After taking My Way, consider the possibility of pregnancy if your period is delayed more than one week beyond the date you expected your period.
- Do not use My Way as routine contraception.
- My Way is not effective in terminating an existing pregnancy.
- My Way does not protect against HIV-infection (AIDS) and other sexually transmitted diseases/infections.
- For women younger than age 17 years, My Way is available only by prescription.

Mfg. by:

Novel laboratories, Inc.
Somerset, NJ

Distributed by:

Gavis Pharmaceuticals, LLC

Somerset, NJ

PI 62030002001

Medication Guide

My Way

Emergency Contraceptive

Because the unexpected happens

Important information about My Way,

Birth Control and Sexually Transmitted Diseases

For additional information intended for healthcare professionals, please see enclosed Product Information for My Way.

What is My Way?

My Way 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.

My Way 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, My Way may work for you.

What My Way is not.

My Way will not work if you are already pregnant and will not affect an existing pregnancy. My Way should not be used as regular birth control. It is important to have another reliable source of birth control that is right for you. My Way will not protect you from HIV infection (the virus that causes

AIDS) and other sexually transmitted diseases.

When is the appropriate time to use My Way?

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

My Way 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 My Way?

- My Way 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. My Way is a backup or emergency method of contraception.
- My Way should not be used if you are already pregnant because it will not work.
- My Way should not be used if you are allergic to levonorgestrel or any other ingredients in My Way.
- My Way 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 My Way work?

My Way is one pill with levonorgestrel, a hormone that has been used in many birth control pills for over 35 years. My Way 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 My Way 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 My Way?

You have only a few days to try to prevent pregnancy after unprotected sex. **The sooner you take My Way, the better it works.** My Way should be taken **as soon as possible within 72 hours (3 days)** after unprotected sex.

How effective is My Way?

The sooner you take My Way, the better it will work. Take My Way 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 My Way worked?

Most women will have their 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 My Way?

There is no medical evidence that My Way would harm a developing baby. If you take My Way (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. My Way 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 My Way, 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 My Way for regular birth control?

No. My Way 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 My Way, it will not help protect you from getting pregnant.

How often can I use My Way?

My Way 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 My Way?

When used as directed, My Way 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 My Way 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 My Way?

My Way does not protect against 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 levonogestrel or any of the ingredients in My Way
- 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 My Way?

Women 17 years of age and older:

- Take My Way as soon as possible within 72 hours (3 days) after unprotected sex.
- If you vomit within 2 hours of taking the medication, call a healthcare professional to find out if you should repeat the dose.
- Prescription only for women younger than age 17. If you are younger than age 17, see a healthcare professional.

What should I do if I have questions about My Way?

If you have questions or need more information about this product, call 1-800-422-8689, visit our website at www.mywaypill.com, or ask a healthcare professional.

Other information

Tablet is 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 1.5 mg

Inactive ingredients: Colloidal silicon dioxide, pregelatinized starch, magnesium stearate, talc, and 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, My Way may work for you. My Way is an emergency contraceptive that helps prevent pregnancy after unprotected sex or when your birth control fails or is not used correctly.

Remember, My Way 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

My Way is used to prevent pregnancy after unprotected sex.

My Way 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 My Way.

The sooner you take My Way, the better it will work.

My Way does not protect against the AIDS virus (HIV) or other sexually transmitted diseases

(STDs)

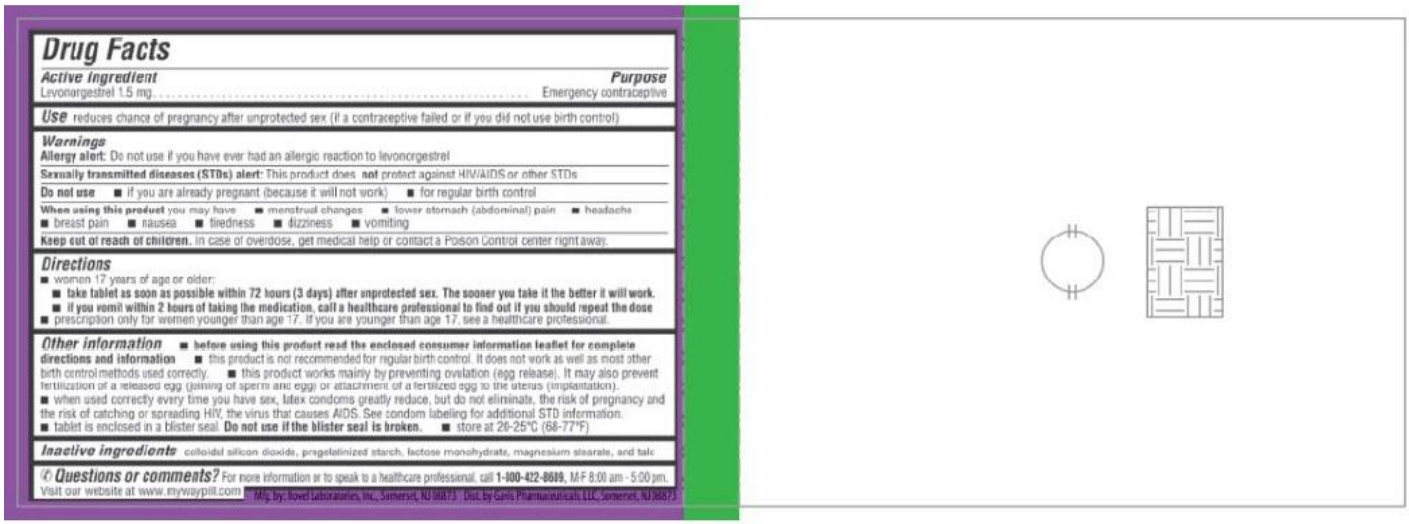
Common side effects associated with the use of My Way include menstrual changes, nausea, lower stomach (abdominal) pain, tiredness, headache, dizziness, breast pain and vomiting.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 43386-620-30

Levonorgestrel Tablet, 1.5 mg

Emergency Contraceptive



Drug Facts

Active Ingredient — **Purpose**
Levonorgestrel 1.5 mg ..... Emergency contraceptive

Use reduces 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
When using this product you may have ■ menstrual changes ■ lower stomach (abdominal) pain ■ headache ■ breast pain ■ nausea ■ tiredness ■ dizziness ■ vomiting
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control center right away.

Directions
■ women 17 years of age or older:
■ **take tablet 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 of taking the medication, call a healthcare professional to find out if you should repeat the dose**
■ prescription only for women younger than age 17. If you are younger than age 17, see a healthcare professional.

Other information ■ **before using this product read the enclosed consumer information leaflet for complete directions and information** ■ this product is not recommended for regular birth control. It does not work as well as most other birth control methods used correctly. ■ 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).
■ when used correctly every time you have sex, latex condoms greatly reduce, but do not eliminate, the risk of pregnancy and the risk of catching or spreading HIV, the virus that causes AIDS. See condom labeling for additional STD information.
■ tablet is enclosed in a blister seal. **Do not use if the blister seal is broken.** ■ store at 26-25°C (68-77°F)

Inactive ingredients colloidal silicon dioxide, pregelatinized starch, lactose monohydrate, magnesium stearate, and talc

Questions or comments? For more information or to speak to a healthcare professional, call **1-800-422-8689**, M-F 8:00 am - 5:00 pm.
Visit our website at www.mywaypill.com Mfg. by: Novel Laboratories, Inc., Somerset, NJ 08873 Dist. by Gavis Pharmaceuticals LLC, Somerset, NJ 08873

FOR POSITION ONLY

FOR POSITION ONLY

PLACE LABEL HERE

FOR POSITION ONLY

Drug Facts

Active Ingredient	Purpose
Levonorgestrel 1.5 mg	Emergency contraceptive

Use reduces 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

When using this product you may have

- menstrual changes
- tiredness
- dizziness
- nausea
- headache
- breast pain
- lower stomach (abdominal) pain
- vomiting

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

Directions

- women 17 years of age or older:
  - **take tablet 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 of taking the medication, call a healthcare professional to find out if you should repeat the dose**

Inactive ingredients colloidal silicon dioxide, pregelatinized starch, lactose monohydrate, magnesium stearate, and talc

Questions or comments? For more information or to speak to a healthcare professional, call **1-800-422-8689**, M-F 8:00 am-5:00 pm. Visit our website at www.myway.com

Mfg. by: Novel Laboratories, Inc., Somerset, NJ 08873
Dist. by: GAVIS Pharmaceuticals, LLC, Somerset, NJ 08873

GAVIS PHARMACEUTICALS

N 3 43386 62030 2

Drug Facts (continued)

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

Other information

- **before using this product read the enclosed consumer information leaflet for complete directions and information**
- this product is not recommended for regular birth control. It does not work as well as most other birth control methods used correctly.
- 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).
- when used correctly every time you have sex, latex condoms greatly reduce, but do not eliminate, the risk of pregnancy and the risk of catching or spreading HIV, the virus that causes AIDS. See condom labeling for additional STD information.
- tablet is enclosed in a blister seal. **Do not use if the blister seal is broken.**
- store at 20-25°C (68-77°F)

My Way™ (Levonorgestrel) Tablet, 1.5 mg

Emergency Contraceptive

Rx only for women younger than age 17

NDC 43386-**620**-30

Rx only for women younger than age 17

My Way™ (Levonorgestrel) Tablet, 1.5 mg

Emergency Contraceptive

Take as soon as possible within 72 hours (3 days) after unprotected sex. The sooner you take it, the better My Way™ will work.

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.

1 Tablet Levonorgestrel 1.5 mg

ONE TABLET EQUALS ONE DOSE

Area for Lot & exp.

My Way™ (Levonorgestrel) Tablet, 1.5 mg

Emergency Contraceptive

Rx only for women younger than age 17

My Way™ (Levonorgestrel) Tablet, 1.5 mg

Emergency Contraceptive

MY WAY

levonorgestrel tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG LABEL	**Item Code (Source)**	NDC:43386-620
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEVONORGESTREL (LEVONORGESTREL)	LEVONORGESTREL	1.5 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE	
STARCH, CORN	
LACTOSE MONOHYDRATE	
MAGNESIUM STEARATE	
TALC	

Product Characteristics

Color	WHITE (off-white)	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43386-620-30	1 in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202508	02/22/2013	

Labeler - GAVIS Pharmaceuticals, LLC. (829838551)

Registrant - GAVIS Pharmaceuticals, LLC. (829838551)

Establishment

Name	Address	ID/FEI	Business Operations
Novel Laboratories, Inc.		793518643	ANALYSIS(43386-620), MANUFACTURE(43386-620)