

HIGHLIGHTS OF PRESCRIBING INFORMATION

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

Previm®

Norgestimate and Ethinyl Estradiol Tablets, USP

0.25 mg/0.035 mg

(nor-JES-ti-mate, ETH-i-nil-es-tra-DYE-ol)

“for oral use”

Initial U.S. Approval: 1989

WARNING: CIGARETTE SMOKING and SERIOUS CARDIOVASCULAR EVENTS
See full prescribing information for complete boxed warning.
• Norgestimate and ethinyl estradiol are contraindicated in women over 35 years old who smoke. (4)
• Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptives (COC) use. (4)

----- **RECENT MAJOR CHANGES** -----
Contraindications (4) 08/2017
Warnings and Precautions (5.3) 08/2017

INDICATIONS AND USAGE

Previm® (norgestimate and ethinyl estradiol tablets) are an estrogen/progestin COCs, indicated for use by women to prevent pregnancy. (1.1)

DOSAGE AND ADMINISTRATION

Take one tablet daily by mouth at the same time every day. (2.2)
Take tablets in the order directed on the blister pack. (2.2)
Do not skip or delay tablet intake. (2.2)

DOSAGE FORMS AND STRENGTHS

Previm® (norgestimate and ethinyl estradiol tablets, USP) consists of 28 round tablets in the following order (3):
• 21 blue tablets each containing 0.25 mg norgestimate and 0.035 mg ethinyl estradiol
• 7 green tablets (inert)

CONTRAINDICATIONS

• High risk of arterial or venous thrombotic diseases (4)
• Liver tumors or liver disease (4)
• Undiagnosed abnormal uterine bleeding (4)
• Pregnancy (4)
• Breast cancer or other estrogen- or progestin-sensitive cancer (4)
• Co-administration with Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir (4)

WARNINGS AND PRECAUTIONS

• **Thromboembolic Disorders and Other Vascular Problems:** Stop norgestimate and ethinyl estradiol if a thrombotic event occurs. Stop at least 4 weeks before and through 2 weeks after major surgery. Start no earlier than 4 weeks after delivery, in women who are not breastfeeding. (5.1)
• **Liver disease:** Discontinue norgestimate and ethinyl estradiol if jaundice occurs. (5.2)
• **High blood pressure:** If used in women with

well-controlled hypertension, monitor blood pressure and stop norgestimate and ethinyl estradiol if blood pressure rises significantly. (5.4)
• **Carbohydrate and lipid metabolic effects:** Monitor prediabetic and diabetic women taking norgestimate and ethinyl estradiol. Consider an alternate contraceptive method for women with uncontrolled dyslipidemia. (5.6)
• **Headache:** Evaluate significant change in headaches and discontinue norgestimate and ethinyl estradiol if indicated. (5.7)
• **Bleeding Irregularities and Amenorrhea:** Evaluate irregular bleeding or amenorrhea. (5.8)

ADVERSE REACTIONS

The most common adverse reactions reported during clinical trials (≥2%) were: Norgestimate and ethinyl estradiol; headache/migraine, abdominal/gastrointestinal pain, vaginal infection, genital discharge, breast issues (including breast pain, discharge, and enlargement), mood disorders (including depression and mood altered), flatulence, nervousness, rash. (6.1)

DRUG INTERACTIONS

Drugs or herbal products that induce certain enzymes including CYP3A4, may decrease the effectiveness of COCs or increase breakthrough bleeding. Counsel patients to use a back-up or alternative method of contraception when enzyme inducers are used with COCs. (7.1)

USE IN SPECIFIC POPULATIONS

Nursing mothers: Not recommended; can decrease milk production. (8.3)

FOR PATIENT COUNSELING INFORMATION AND FDA-approved patient labeling.

Revised: 12/2018

FULL PRESCRIBING INFORMATION

WARNING: CIGARETTE SMOKING and SERIOUS CARDIOVASCULAR EVENTS
Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptive (COC) use. This risk increases with age, particularly in women over 35 years of age, and with the number of cigarettes smoked. For this reason, COCs are contraindicated in women who are over 35 years of age and smoke [see CONTRAINDICATIONS (4)].

INDICATIONS AND USAGE

1.1 Oral Contraceptive
Previm® (norgestimate and ethinyl estradiol tablets), are indicated for use by females of reproductive potential to prevent pregnancy [see CLINICAL STUDIES (14)].

DOSAGE AND ADMINISTRATION

2.1 How to Start Previm®
Previm® (norgestimate and ethinyl estradiol tablets), are dispensed in a blister pack [see HOW SUPPLIED/STORAGE AND HANDLING (16)]. Previm® may be started using either a Day 1 start or a Sunday start (see Table 1). For the first cycle of a Sunday Start regimen, an additional method of contraception should be used until after the first 7 consecutive days of administration.

How to Take Previm®

Table 1: Instructions for Administration of Previm®

Starting COCs in women not currently using hormonal contraception (Day 1 Start or Sunday Start)	Day 1 Start: • Take first active tablet without regard to meals on the first day of menses. • Take subsequent active tablets once daily at the same time each day for a total of 21 days. • Take one green inactive tablet daily for 7 days and at the same time of day that active tablets were taken. • Begin each subsequent blister pack on the same day of Previm® the week as the first cycle blister pack (i.e., on the day after taking the last inactive tablet)
Important: Consider the possibility of ovulation and conception prior to initiation of this product.	Sunday Start: • Take first active tablet without regard to meals on the first Sunday after the onset of menses. Due to the potential risk of becoming pregnant, use additional non-hormonal contraception (such as condoms and spermicide) for the first seven days of the patient's first cycle blister pack of Previm®. • Take subsequent active tablets once daily at the same time each day for a total of 21 days. • Take one green inactive tablet daily for the following 7 days and at the same time of day that active tablets were taken. • Begin each subsequent blister pack on the same day of the week as the first cycle blister pack (i.e., on the day after taking the last inactive tablet)
Tablet Color: • Previm® active tablets are blue (Day 1 to Day 21). • Previm® has green inactive tablets (Day 22 to Day 28).	• Take subsequent active tablets once daily at the same time each day for a total of 21 days. • Take one green inactive tablet daily for the following 7 days and at the same time of day that active tablets were taken. • Begin each subsequent blister pack on the same day of the week as the first cycle blister pack (i.e., on the Sunday after taking the last inactive tablet) and the additional non-hormonal contraceptive is not needed.
Switching to Previm® from another oral contraceptive	Start on the same day that a new blister pack of the previous oral contraceptive would have started.
Switching from another contraceptive method to Previm®	Start Previm®:
• Transdermal patch	• On the day when next application would have been scheduled
• Vaginal ring	• On the day when next insertion would have been scheduled
• Injection	• On the day when next injection would have been scheduled
• Intrauterine contraceptive	• On the day of removal • If the IUD is not removed on first day of the patient's menstrual cycle, additional non-hormonal contraceptive (such as condoms and spermicide) is needed for the first seven days of the first cycle blister pack.
• Implant	• On the day of removal

Complete instructions to facilitate patient counseling on proper tablet usage are located in the FDA-Approved Patient Labeling.

Starting Previm® after Abortion or Miscarriage

First-trimester
• After a first-trimester abortion or miscarriage, Previm® may be started immediately. An additional method of contraception is not needed if Previm® is started immediately.
• If Previm® is not started within 5 days after termination of the pregnancy, the patient should use additional non-hormonal contraception (such as condoms and spermicide) for the first seven days of her first cycle blister pack of Previm®.

Second-trimester
• Do not start until 4 weeks after a second-trimester abortion or miscarriage, due to the increased risk of thromboembolic disease. Start Previm®, following the instructions in Table 1 for Day 1 or Sunday start, as desired. If using Sunday start, use additional non-hormonal contraception (such as condoms and spermicide) for the first seven days of the patient's first cycle blister pack of Previm® [see CONTRAINDICATIONS (4), WARNINGS AND PRECAUTIONS (5.1), and FDA-APPROVED PATIENT LABELING].

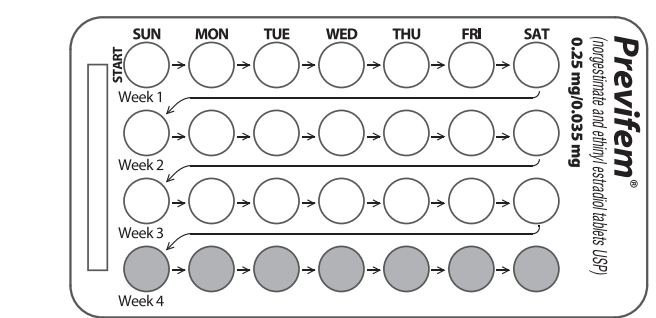
Starting Previm® after Childbirth
• Do not start until 4 weeks after delivery, due to the increased risk of thromboembolic disease. Start contraceptive therapy with Previm® following the instructions in Table 1 for women not currently using hormonal contraception.
• Previm® is not recommended for use in lactating women [see USE IN SPECIFIC POPULATIONS (8.3)].
• If the woman has not yet had a period postpartum, consider the possibility of ovulation and conception occurring prior to use of Previm®. [See CONTRAINDICATIONS (4), WARNINGS AND PRECAUTIONS (5.1), USE IN SPECIFIC POPULATIONS (8.1 and 8.3), and FDA-Approved Patient Labeling].

BEFORE YOU START TAKING YOUR PILLS

- 1. DECIDE WHAT TIME OF DAY YOU WANT TO TAKE YOUR PILL.**
It is important to take it at about the same time every day.
- 2. LOOK AT YOUR PILL PACK.**
The pill blister pack has 21 active pills (with hormones) to take for 3 weeks. This is followed by 1 week of reminder green pills (without hormones). There are 21 blue active pills, and 7 green reminder pills.

ALSO FIND:

- 1) where on the blister pack to start taking pills,
- 2) in what order to take the pills (follow the arrows)
- 3) The week numbers as shown in the diagram below.



BE SURE YOU HAVE READY AT ALL TIMES:

Another kind of birth control (such as a condom or spermicide) to use as a back-up method in case you miss pills.
An extra, full pill blister pack.

Missed Tablets

Table 2: Instructions for Missed Previm® Tablets	Take the tablet as soon as possible. Continue taking one tablet a day until the blister pack is finished.
• If one active tablet is missed in Weeks 1, 2, or 3	
• If two active tablets are missed in Week 1 or Week 2	Take the two missed tablets as soon as possible and the next two active tablets the next day. Continue taking one tablet a day until the blister pack is finished. Additional non-hormonal contraception (such as condoms and spermicide) should be used as back-up if the patient has sex within 7 days after missing tablets.
• If two active tablets are missed in the third week or three or more active tablets are missed in a row in Weeks 1, 2, or 3	Day 1 start: Throw out the rest of the blister pack and start a new pack that same day. Sunday start: Continue taking one tablet a day until Sunday, then throw out the rest of the blister pack and start a new blister pack that same day. Additional non-hormonal contraception (such as condoms and spermicide) should be used as back-up if the patient has sex within 7 days after missing tablets.

Advice in Case of Gastrointestinal Disturbances

In case of severe vomiting or diarrhea, absorption may not be complete and additional contraceptive measures should be taken. If vomiting or diarrhea occurs within 3 to 4 hours after taking an active tablet, handle this as a missed tablet [see FDA-Approved Patient Labeling].

DOSAGE FORMS AND STRENGTHS

Previm® is available in blister cards. Each blister pack contains 28 tablets in the following order:
• 21 active tablets are blue, round, debossed with E on one side and T4 on the other side.
• 7 inert tablets are green, round, debossed with E on one side and J1 on the other side.

CONTRAINDICATIONS

Do not prescribe norgestimate and ethinyl estradiol to women who are known to have the following conditions:

- A high risk of arterial or venous thrombotic diseases. Examples include women who are known to:
 - Smoke, if over age 35 [see BOXED WARNING and WARNINGS AND PRECAUTIONS (5.1)]
 - Have deep vein thrombosis or pulmonary embolism, now or in the past [see WARNINGS AND PRECAUTIONS (5.1)]
 - Have inherited or acquired hypercoagulopathies [see WARNINGS AND PRECAUTIONS (5.1)]
 - Have cerebrovascular disease [see WARNINGS AND PRECAUTIONS (5.1)]
 - Have coronary artery disease [see WARNINGS AND PRECAUTIONS (5.1)]
 - Have thrombogenic valvular or thrombogenic rhythm diseases of the heart (for example, subacute bacterial endocarditis with valvular disease, or atrial fibrillation) [see WARNINGS AND PRECAUTIONS (5.1)]
 - Have uncontrolled hypertension [see WARNINGS AND PRECAUTIONS (5.4)]
 - Have diabetes mellitus with vascular disease [see WARNINGS AND PRECAUTIONS (5.6)]
 - Have headaches with focal neurological symptoms or migraine headaches with aura [see WARNINGS AND PRECAUTIONS (5.7)]
- Women over age 35 with any migraine headaches [see WARNINGS AND PRECAUTIONS (5.7)]
- Liver tumors, benign or malignant, or liver disease [see WARNINGS AND PRECAUTIONS (5.2)]
- Undiagnosed abnormal uterine bleeding [see WARNINGS AND PRECAUTIONS (5.8)]
- Pregnancy, because there is no reason to use COCs during pregnancy [see WARNINGS AND PRECAUTIONS (5.9) and USE IN SPECIFIC POPULATIONS (8.1)]
- Breast cancer or other estrogen- or progestin-sensitive cancer, now or in the past [see WARNINGS AND PRECAUTIONS (5.11)]
- Use of Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, due to the potential for ALT elevations [see WARNINGS AND PRECAUTIONS (5.3)]

WARNINGS AND PRECAUTIONS

5.1 Thromboembolic Disorders and Other Vascular Problems
• Stop norgestimate and ethinyl estradiol if an arterial thrombotic event or venous thromboembolic (VTE) event occurs.
• Stop norgestimate and ethinyl estradiol if there is unexplained loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions. Evaluate for retinal vein thrombosis immediately [see ADVERSE REACTIONS (6.2)].
• If feasible, stop norgestimate and ethinyl estradiol at least 4 weeks before and through 2 weeks after major surgery or other surgeries known to have an elevated risk of VTE as well as during and following prolonged immobilization.
• Start norgestimate and ethinyl estradiol no earlier than 4 weeks after delivery, in women who are not breastfeeding. The risk of postpartum VTE decreases after the third postpartum week, whereas the risk of ovulation increases after the third postpartum week.

5.2 Effect on Binding Globulins
The estrogen component of COCs may raise the serum concentrations of thyroxine-binding globulin, sex hormone-binding globulin, and cortisol-binding globulin. The dose of replacement thyroid hormone or cortisol therapy may need to be increased.

5.3 Monitoring
A woman who is taking COCs should have a yearly visit with her healthcare provider for a blood pressure check and for other indicated healthcare.

5.4 Hereditary Angioedema
In women with hereditary angioedema, exogenous estrogens may induce or exacerbate symptoms of angioedema.

5.5 Chloasma
Chloasma may occasionally occur, especially in women with a history of chloasma gravidarum. Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation while taking norgestimate and ethinyl estradiol.

5.6 High Blood Pressure
Norgestimate and ethinyl estradiol is contraindicated in women with uncontrolled hypertension or hypertension with vascular disease [see CONTRAINDICATIONS (4)]. For women with well-controlled hypertension, monitor blood pressure and stop norgestimate and ethinyl estradiol if blood pressure rises significantly.
An increase in blood pressure has been reported in women taking COCs, and this increase is more likely in older women with extended duration of use. The incidence of hypertension increases with increasing concentrations of progestin.

5.7 Headache
If a woman taking norgestimate and ethinyl estradiol develops new headaches that are recurrent, persistent, or severe, evaluate the cause and discontinue norgestimate and ethinyl estradiol if indicated. Consider discontinuation of norgestimate and ethinyl estradiol in the case of increased frequency or severity of migraine during COC use (which may be prodromal of a cerebrovascular event).

5.8 Bleeding Irregularities and Amenorrhea
Unscheduled Bleeding and Spotting
Unscheduled (breakthrough or intermenstrual) bleeding and spotting sometimes occur in patients on COCs, especially during the first three months of use. If bleeding persists or occurs after previously regular cycles, check for causes such as pregnancy or malignancy. If pathology and pregnancy are excluded, bleeding irregularities may resolve over time or with a change to a different contraceptive product.
In clinical trials of norgestimate and ethinyl estradiol, the frequency and duration of breakthrough bleeding and/or spotting was assessed in 11,647 patients (21,275 evaluable cycles) and 4,926 patients (35,546 evaluable cycles), respectively. A total of 100 (7.5%) women discontinued norgestimate and ethinyl estradiol, at least in part, due to bleeding or spotting. Based on data from the clinical trials, 14 to 34% of women using norgestimate and ethinyl estradiol experienced unscheduled bleeding per cycle in the first year. The percent of women who experienced breakthrough/unscheduled bleeding tended to decrease over time.

5.9 Amenorrhea and Oligomenorrhea
Women who use norgestimate and ethinyl estradiol may experience amenorrhea. Some women may experience amenorrhea or oligomenorrhea after discontinuation of COCs, especially when such a condition was pre-existing.
If scheduled (withdrawal) bleeding does not occur, consider the possibility of pregnancy. If the patient has not adhered to the prescribed dosing schedule (missed one or more active tablets or started taking them on a day later than she should have), consider the possibility of pregnancy at the time of the first missed period and take appropriate diagnostic measures. If the patient has adhered to the prescribed regimen and misses two consecutive periods, rule out pregnancy.

5.9 COC Use Before or During Early Pregnancy
Extensive epidemiological studies have revealed no increased risk of birth defects in women who have used oral contraceptives prior to pregnancy. Studies also do not suggest a teratogenic effect, particularly in so far as cardiac anomalies and limb reduction defects are concerned, when oral contraceptives are taken inadvertently during early pregnancy. Discontinue norgestimate and ethinyl estradiol use if pregnancy is confirmed.
Administration of COCs to induce withdrawal bleeding should not be used as a test for pregnancy [see USE IN SPECIFIC POPULATIONS (8.1)].

5.10 Depression
Carefully observe women with a history of depression and discontinue norgestimate and ethinyl estradiol if depression recurs to a serious degree.

5.11 Carcinoma of Breast and Cervix
• Norgestimate and ethinyl estradiol is contraindicated in women who currently have or have had breast cancer because breast cancer may be hormonally sensitive [see CONTRAINDICATIONS (4)]. There is substantial evidence that COCs do not increase the incidence of breast cancer. Although some past studies have suggested that COCs might increase the incidence of breast cancer, more recent studies have not confirmed such findings.
• Some studies suggest that COC use has been associated with an increase in the risk of cervical cancer or intraepithelial neoplasia. However, there continues to be controversy about the extent to which such findings may be due to differences in sexual behavior and other factors.

5.12 Effect on Binding Globulins
The estrogen component of COCs may raise the serum concentrations of thyroxine-binding globulin, sex hormone-binding globulin, and cortisol-binding globulin. The dose of replacement thyroid hormone or cortisol therapy may need to be increased.

5.13 Monitoring
A woman who is taking COCs should have a yearly visit with her healthcare provider for a blood pressure check and for other indicated healthcare.

5.14 Hereditary Angioedema
In women with hereditary angioedema, exogenous estrogens may induce or exacerbate symptoms of angioedema.

5.15 Chloasma
Chloasma may occasionally occur, especially in women with a history of chloasma gravidarum. Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation while taking norgestimate and ethinyl estradiol.

Liver Disease

Impaired Liver Function
Do not use norgestimate and ethinyl estradiol in women with liver disease, such as acute viral hepatitis or severe (decompensated) cirrhosis of liver [see CONTRAINDICATIONS (4)]. Acute or chronic disturbances of liver function may necessitate the discontinuation of COC use until markers of liver function return to normal and COC causation has been excluded. Discontinue norgestimate and ethinyl estradiol if jaundice develops.

Liver Tumors

Norgestimate and ethinyl estradiol is contraindicated in women with benign and malignant liver tumors [see CONTRAINDICATIONS (4)]. Hepatic adenomas are associated with COC use. An estimate of the attributable risk is 3.3 cases/100,000 COC users. Rupture of hepatic adenomas may cause death through intra-abdominal hemorrhage.
Studies have shown an increased risk of developing hepatocellular carcinoma in long-term (≥8 years) COC users. However, the risk of liver cancers in COC users is less than one case per million users.

Risk of Liver Enzyme Elevations with Concomitant Hepatitis C Treatment

During clinical trials with the Hepatitis C combination drug regimen that contains ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, ALT elevations greater than 5 times the upper limit of normal (ULN), including some cases greater than 20 times the ULN, were significantly more frequent in women using ethinyl estradiol-containing medications, such as COCs. Discontinue norgestimate and ethinyl estradiol prior to starting therapy with the combination drug regimen ombitasvir/paritaprevir/ritonavir, with or without dasabuvir [see CONTRAINDICATIONS (4)]. Norgestimate and ethinyl estradiol can be restarted approximately 2 weeks following completion of treatment with the Hepatitis C combination drug regimen.

High Blood Pressure

Norgestimate and ethinyl estradiol is contraindicated in women with uncontrolled hypertension or hypertension with vascular disease [see CONTRAINDICATIONS (4)]. For women with well-controlled hypertension, monitor blood pressure and stop norgestimate and ethinyl estradiol if blood pressure rises significantly.
An increase in blood pressure has been reported in women taking COCs, and this increase is more likely in older women with extended duration of use. The incidence of hypertension increases with increasing concentrations of progestin.

Gallbladder Disease

Studies suggest a small increased relative risk of developing gallbladder disease among COC users. Use of COCs may worsen existing gallbladder disease. A past history of COC-related cholelithiasis predicts an increased risk with subsequent COC use. Women with a history of pregnancy-related cholelithiasis may be at an increased risk for COC related cholelithiasis.

Carbohydrate and Lipid Metabolic Effects

COCs may decrease glucose tolerance.
Consider alternative contraception for women with uncontrolled dyslipidemia. A small proportion of women will have adverse lipid changes while on COCs.
Women with hypertriglyceridemia, or a family history thereof, may be at an increased risk of pancreatitis when using COCs.

Headache

If a woman taking norgestimate and ethinyl estradiol develops new headaches that are recurrent, persistent, or severe, evaluate the cause and discontinue norgestimate and ethinyl estradiol if indicated. Consider discontinuation of norgestimate and ethinyl estradiol in the case of increased frequency or severity of migraine during COC use (which may be prodromal of a cerebrovascular event).

Bleeding Irregularities and Amenorrhea

Unscheduled Bleeding and Spotting
Unscheduled (breakthrough or intermenstrual) bleeding and spotting sometimes occur in patients on COCs, especially during the first three months of use. If bleeding persists or occurs after previously regular cycles, check for causes such as pregnancy or malignancy. If pathology and pregnancy are excluded, bleeding irregularities may resolve over time or with a change to a different contraceptive product.
In clinical trials of norgestimate and ethinyl estradiol, the frequency and duration of breakthrough bleeding and/or spotting was assessed in 11,647 patients (21,275 evaluable cycles) and 4,926 patients (35,546 evaluable cycles), respectively. A total of 100 (7.5%) women discontinued norgestimate and ethinyl estradiol, at least in part, due to bleeding or spotting. Based on data from the clinical trials, 14 to 34% of women using norgestimate and ethinyl estradiol experienced unscheduled bleeding per cycle in the first year. The percent of women who experienced breakthrough/unscheduled bleeding tended to decrease over time.

Amenorrhea and Oligomenorrhea

Women who use norgestimate and ethinyl estradiol may experience amenorrhea. Some women may experience amenorrhea or oligomenorrhea after discontinuation of COCs, especially when such a condition was pre-existing.
If scheduled (withdrawal) bleeding does not occur, consider the possibility of pregnancy. If the patient has not adhered to the prescribed dosing schedule (missed one or more active tablets or started taking them on a day later than she should have), consider the possibility of pregnancy at the time of the first missed period and take appropriate diagnostic measures. If the patient has adhered to the prescribed regimen and misses two consecutive periods, rule out pregnancy.

COC Use Before or During Early Pregnancy

Extensive epidemiological studies have revealed no increased risk of birth defects in women who have used oral contraceptives prior to pregnancy. Studies also do not suggest a teratogenic effect, particularly in so far as cardiac anomalies and limb reduction defects are concerned, when oral contraceptives are taken inadvertently during early pregnancy. Discontinue norgestimate and ethinyl estradiol use if pregnancy is confirmed.
Administration of COCs to induce withdrawal bleeding should not be used as a test for pregnancy [see USE IN SPECIFIC POPULATIONS (8.1)].

Depression

Carefully observe women with a history of depression and discontinue norgestimate and ethinyl estradiol if depression recurs to a serious degree.

Carcinoma of Breast and Cervix

• Norgestimate and ethinyl estradiol is contraindicated in women who currently have or have had breast cancer because breast cancer may be hormonally sensitive [see CONTRAINDICATIONS (4)]. There is substantial evidence that COCs do not increase the incidence of breast cancer. Although some past studies have suggested that COCs might increase the incidence of breast cancer, more recent studies have not confirmed such findings.
• Some studies suggest that COC use has been associated with an increase in the risk of cervical cancer or intraepithelial neoplasia. However, there continues to be controversy about the extent to which such findings may be due to differences in sexual behavior and other factors.

Effect on Binding Globulins

The estrogen component of COCs may raise the serum concentrations of thyroxine-binding globulin, sex hormone-binding globulin, and cortisol-binding globulin. The dose of replacement thyroid hormone or cortisol therapy may need to be increased.

Monitoring

A woman who is taking COCs should have a yearly visit with her healthcare provider for a blood pressure check and for other indicated healthcare.

Hereditary Angioedema

In women with hereditary angioedema, exogenous estrogens may induce or exacerbate symptoms of angioedema.

Chloasma

Chloasma may occasionally occur, especially in women with a history of chloasma gravidarum. Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation while taking norgestimate and ethinyl estradiol.

ADVERSE REACTIONS

The following serious adverse reactions with the use of COCs are discussed elsewhere in labeling:
• Serious cardiovascular events and stroke [see BOXED WARNING and WARNINGS AND PRECAUTIONS (5.1)]
• Vascular events [see WARNINGS AND PRECAUTIONS (5.1)]
• Liver disease [see WARNINGS AND PRECAUTIONS (5.2)]

Adverse reactions commonly reported by COC users are:

- Irregular uterine bleeding
- Nausea
- Breast tenderness
- Headache

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.
The safety of norgestimate and ethinyl estradiol was evaluated in 1,647 healthy women of child-bearing potential who participated in 3 clinical trials and received at least 1 dose of norgestimate and ethinyl estradiol for contraception. Two trials were randomized active-controlled trials and 1 was an uncontrolled open-label trial. In all 3 trials, subjects were followed for up to 24 cycles.

Common Adverse Reactions (≥ 2% of subjects): The most common adverse reactions reported by at least 2% of the 1,647 women were the following in order of decreasing incidence: headache/migraine (32.9%), abdominal/gastrointestinal pain (7.8%), vaginal infection (8.4%), genital discharge (6.8%), breast issues (including breast pain, discharge, and enlargement) (6.3%), mood disorders (including depression and mood altered) (5%), flatulence (3.2%), nervousness (2.9%), and rash (2.6%).

Adverse Reactions Leading to Study Discontinuation: Over the three trials, between 11 to 21% of subjects discontinued the trial due to an adverse reaction. The most common adverse reactions (≥1%) leading to discontinuation were: metrorrhagia (6.9%), nausea/vomiting (5%), headache (4.1%), mood disorders (including depression and mood altered) (2.4%), premenstrual syndrome (1.7%), hypertension (1.4%), breast pain (1.4%), nervousness (1.3%), amenorrhea (1.1%), dysmenorrhea (1.1%), weight increase (1.1%), and flatulence (1.1%).

Serious Adverse Reactions: breast cancer (1 subject), mood disorders including depression, irritability, and mood swings (1 subject), myocardial infarction (1 subject), and venous thromboembolic events including pulmonary embolism (1 subject) and deep vein thrombosis (DVT) (1 subject).

Postmarketing Experience

The following additional adverse drug reactions have been reported from worldwide postmarketing experience with norgestimate and ethinyl estradiol. 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.

Infections and Infestations: Urinary tract infection;

Neoplasms Benign, Malignant and Unspecified (Incl. Cysts and Polyps): Breast cancer, benign breast neoplasm, hepatic adenoma, focal nodular hyperplasia, breast cyst;

Immune System Disorders: Hypersensitivity;

Metabolism and Nutrition Disorders: Dyslipidemia;

Psychiatric Disorders: Anxiety, insomnia;

Nervous System Disorders: Syncope, convulsion, paresthesia, dizziness;

Eye Disorders: Visual impairment, dry eye, contact lens intolerance;

Ear and Labyrinth Disorders: Vertigo;

Cardiac Disorders: Tachycardia, palpitations;

Vascular Events: Deep vein thrombosis, pulmonary embolism, retinal vascular thrombosis, hot flash;

Arterial Events: Arterial thromboembolism, myocardial infarction, cerebrovascular accident;

Respiratory, Thoracic and Mediastinal Disorders: Dyspnea;

Gastrointestinal Disorders: Pancreatitis, abdominal distention, diarrhea, constipation;

Hepatobiliary Disorders: Hepatitis;

Skin and Subcutaneous Tissue Disorders: Angioedema, erythema nodosum, hirsutism, night sweats, hyperhidrosis, photosensitivity reaction, ur

Food Effect

The effect of food on the pharmacokinetics of norgestimate and ethinyl estradiol has not been studied.

Distribution

NGMN and NG are highly bound (>97%) to serum proteins. NGMN is bound to albumin and not to SHBG, while NG is bound primarily to SHBG. EE is extensively bound (>97%) to serum albumin and induces an increase in the serum concentrations of SHBG.

Metabolism

NGM is extensively metabolized by first-pass mechanisms in the gastrointestinal tract and/or liver. NGM's primary active metabolite is NGMN. Subsequent hepatic metabolism of NGMN occurs and metabolites include NG, which is also active, and various hydroxylated and conjugated metabolites. Although NGMN and its metabolites inhibit a variety of P450 enzymes in human liver microsomes, under the recommended dosing regimen, the *in vivo* concentrations of NGMN and its metabolites, even at the peak serum levels, are relatively low compared to the inhibitory constant (K_i). EE is also metabolized to various hydroxylated products and their glucuronide and sulfate conjugates.

Excretion

The metabolites of NGMN and EE are eliminated by renal and fecal pathways. Following administration of ¹⁴C-norgestimate, 47% (45 to 49%) and 37% (16 to 49%) of the administered radioactivity was eliminated in the urine and feces, respectively. Unchanged NGM was not detected in the urine. In addition to 17-deacetyl norgestimate, a number of metabolites of NGM have been identified in human urine following administration of radiolabeled NGM. These include 18, 19-Dinor-17-pregn-4-en-20-yn-3-one, 17-hydroxy-13-ethyl, (17a)-; 18, 19-Dinor-5β-17-pregnan-20-yn-3α, 17β-dihydroxy-13-ethyl, (17a), various hydroxylated metabolites and conjugates of these metabolites.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

[See **WARNINGS AND PRECAUTIONS** (5.2, 5.11) and **USE IN SPECIFIC POPULATIONS** (8.1).]

14 CLINICAL STUDIES

14.1 Contraception

In three US clinical trials with norgestimate and ethinyl estradiol, 1,651 women aged 18 to 38 years were studied for up to 24 cycles, proving a total of 24,272 cycles of exposure. The racial demographic was about 73 to 86% Caucasian, 8 to 13% African-American, 6 to 14% Hispanic with the remainder Asian or Other (≤1%). There were no exclusions on the basis of weight; the weight range for women treated was 82 to 303 lbs, with a mean weight of about 135 lbs. The pregnancy rate was approximately 1 pregnancy per 100 women-years.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

Previfem[®] (norgestimate and ethinyl estradiol tablets, USP) are available in blisters containing 28 tablets as follows:

Each blister card contains 21 active tablets and 7 inactive tablets. The 21 active tablets are blue, round, debossed with E on one side and 14 on the other side. The 7 inert tablets are green, round, debossed with E on one side and J1 on the other side.

NDC 0254-2029-91, one box containing 1 individual unit carton

NDC 0254-2029-80, one box containing 6 individual unit cartons

16.2 Storage Conditions

- Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room temperature].
- Protect from light.
- Keep out of the reach of children

17 PATIENT COUNSELING INFORMATION

See **FDA-approved patient labeling (Patient Information and Instructions for Use)**.

Counsel patients about the following information:

- Cigarette smoking increases the risk of serious cardiovascular events from COC use, and that women who are over 35 years old and smoke should not use COCs [see **BOXED WARNING**].
- Increased risk of VTE compared to non-users of COCs is greatest after initially starting a COC or restarting (following a 4-week or greater pill-free interval) the same or a different COC [see **WARNINGS AND PRECAUTIONS** (5.1)].
- Previfem[®] does not protect against HIV infection (AIDS) and other sexually transmitted infections.
- Previfem[®] is not to be used during pregnancy; if pregnancy occurs during use of Previfem[®] instruct the patient to stop further use [see **WARNINGS AND PRECAUTIONS** (5.9)].
- Take one tablet daily by mouth at the same time every day. Instruct patients what to do in the event tablets are missed [see **DOSAGE AND ADMINISTRATION** (2.2)].
- Use a back-up or alternative method of contraception when enzyme inducers are used with Previfem[®] [see **DRUG INTERACTIONS** (7.1)].
- COCs may reduce breast milk production; this is less likely to occur if breastfeeding is well established [see **USE IN SPECIFIC POPULATIONS** (8.3)].
- Women who start COCs postpartum, and who have not yet had a period, should use an additional method of contraception until they have taken an active tablet for 7 consecutive days [see **DOSAGE AND ADMINISTRATION** (2.2)].
- Amenorrhea may occur. Consider pregnancy in the event of amenorrhea at the time of the first missed period. Rule out pregnancy in the event of amenorrhea in two or more consecutive cycles [see **WARNINGS AND PRECAUTIONS** (6.8)].

Manufactured by: Laboratorios León Farma S.A., Spain

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Patient Information

Previfem[®] (norgestimate and ethinyl estradiol tablets, USP) (nor-JES-ti-mate, ETH-i-nil es-tra-DYE-ol)

What is the most important information I should know about Previfem[®]?

Do not use Previfem[®] if you smoke cigarettes and are over 35 years old. Smoking increases your risk of serious cardiovascular side effects from hormonal birth control pills, including death from heart attack, blood clots or stroke. This risk increases with age and the number of cigarettes you smoke.

What is Previfem[®]?

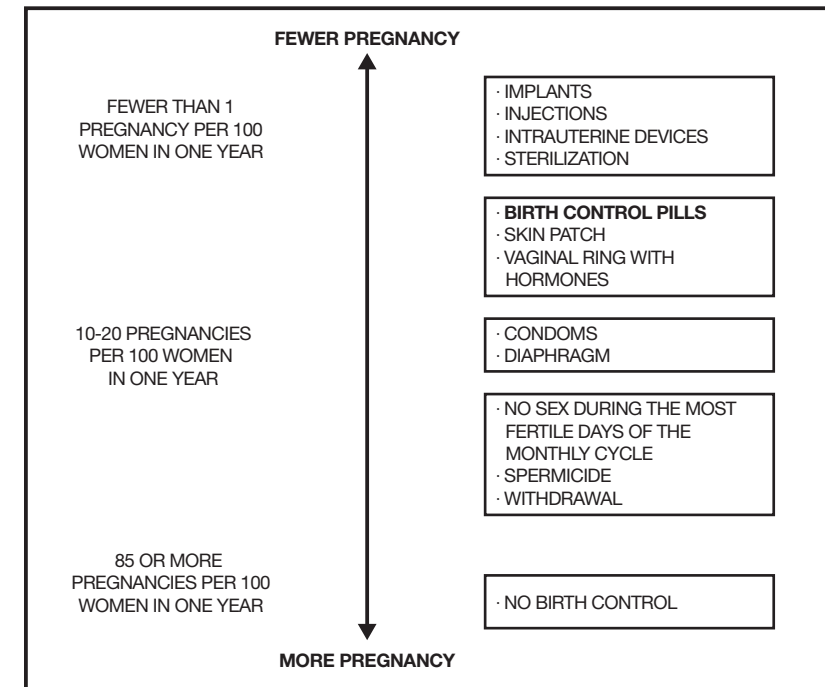
Previfem[®] is a birth control pill (oral contraceptive) used by women to prevent pregnancy.

How does Previfem[®] work for contraception?

Your chance of getting pregnant depends on how well you follow the directions for taking your birth control pills. The better you follow the directions, the less chance you have of getting pregnant.

Based on the results of clinical studies, about 1 out of 100 women may get pregnant during the first year they use Previfem[®].

The following chart shows the chance of getting pregnant for women who use different methods of birth control. Each box on the chart contains a list of birth control methods that are similar in effectiveness. The most effective methods are at the top of the chart. The box on the bottom of the chart shows the chance of getting pregnant for women who do not use birth control and are trying to get pregnant.



Who should not take Previfem[®]?

Do not take Previfem[®] if you:

- smoke and are over 35 years of age
- had blood clots in your arms, legs, lungs, or eyes
- had a problem with your blood that makes it clot more than normal
- have certain heart valve problems or irregular heart beat that increases your risk of having blood clots
- had a stroke
- had a heart attack
- have high blood pressure that cannot be controlled by medicine
- have diabetes with kidney, eye, nerve, or blood vessel damage
- have certain kinds of severe migraine headaches with aura, numbness, weakness or changes in vision, or any migraine headaches if you are over 35 years of age
- have liver problems, including liver tumors
- take any Hepatitis C drug combination containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir. This may increase levels of the liver enzyme "alanine aminotransferase" (ALT) in the blood.
- have any unexplained vaginal bleeding
- are pregnant
- had breast cancer or any cancer that is sensitive to female hormones

If any of these conditions happen while you are taking Previfem[®], stop taking Previfem[®] right away and talk to your healthcare provider. Use non-hormonal contraception when you stop taking Previfem[®].

What should I tell my healthcare provider before taking Previfem[®]? Tell your healthcare provider if you:

- are pregnant or think you may be pregnant
- are depressed now or have been depressed in the past
- had yellowing of your skin or eyes (jaundice) caused by pregnancy (Cholestasis of pregnancy)
- are breastfeeding or plan to breastfeed. Previfem[®] may decrease the amount of breast milk you make. A small amount of the hormones in Previfem[®] may pass into your breast milk. Talk to your healthcare provider about the best birth control method for you while breastfeeding.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

Previfem[®] may affect the way other medicines work, and other medicines may affect how well Previfem[®] works.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take Previfem[®]?

Read the **Instructions for Use** at the end of this Patient Information.

What are the possible serious side effects of Previfem[®]?

- Like pregnancy, Previfem[®] may cause serious side effects, including blood clots in your lungs, heart attack, or a stroke that may lead to death. Some other examples of serious blood clots include blood clots in the legs or eyes.**

Serious blood clots can happen especially if you are obese, are over 35 years of age. Serious blood clots are more likely to happen when you:

- First start taking birth control pills
- Restart the same or different birth control pills after not using them for a month or more

Call your healthcare provider or go to a hospital emergency room right away if you have:

- leg pain that will not go away
- a sudden, severe headache unlike your usual headaches
- sudden severe shortness of breath
- weakness or numbness in your arm or leg
- sudden change in vision or blindness
- trouble speaking
- chest pain

Other serious side effects include:

- liver problems, including:**
 - rare liver tumors
 - jaundice (cholestasis), especially if you previously had cholestasis of pregnancy. Call your healthcare provider if you have yellowing of your skin or eyes.
- high blood pressure.** You should see your healthcare provider for a yearly check of your blood pressure.
- gallbladder problems**
- changes in the sugar and fat (cholesterol and triglycerides) levels in your blood**
- new or worsening headaches including migraine headaches**
- irregular or unusual vaginal bleeding and spotting between your menstrual periods, especially during the first 3 months of taking Previfem[®].**
- depression**
- possible cancer in your breast and cervix**
- swelling of your skin especially around your mouth, eyes, and in your throat (angioedema).**

Call your healthcare provider if you have a swollen face, lips, mouth tongue or throat, which may lead to difficulty swallowing or breathing. Your chance of having angioedema is higher if you have a history of angioedema.

- dark patches of skin around your forehead, nose, cheeks and around your mouth, especially during pregnancy (chloasma).** Women who tend to get chloasma should avoid spending a long time in sunlight, tanning booths, and under sun lamps while taking Previfem[®]. Use sunscreen if you have to be in the sunlight.

What are the most common side effects of Previfem[®]?

- headache (migraine)
- breast pain or tenderness, enlargement or discharge
- stomach pain, discomfort, and gas
- vaginal infections and discharge
- mood changes, including depression
- nervousness
- changes in weight
- skin rash

These are not all the possible side effects of Previfem[®]. For more information, ask your healthcare provider or pharmacist.

You may report side effects to Par Pharmaceuticals at 1-800-828-9393, or FDA at 1800-FDA-1088.

What else should I know about taking Previfem[®]?

- If you are scheduled for any lab tests, tell your healthcare provider you are taking Previfem[®].
- Certain blood tests may be affected by Previfem[®].
- Previfem[®] does not protect against HIV infection (AIDS) and other sexually transmitted infections.

How should I store Previfem[®]?

- Store Previfem[®] at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep Previfem[®] and all medicines out of the reach of children.
- Store away from light.

General information about the safe and effective use of Previfem[®].

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Previfem[®] for a condition for which it was not prescribed. Do not give Previfem[®] to other people, even if they have the same symptoms that you have.

This Patient Information summarizes the most important information about Previfem[®]. You can ask your pharmacist or healthcare provider for information about Previfem[®] that is written for health professionals. For more information, call Par Pharmaceutical at 1-800-828-9393.

Do birth control pills cause cancer?

Birth control pills do not seem to cause breast cancer. However, if you have breast cancer now, or have had it in the past, do not use birth control pills because some breast cancers are sensitive to hormones.

Women who use birth control pills may have a slightly higher chance of getting cervical cancer. However, this may be due to other reasons such as having more sexual partners.

What if I want to become pregnant?

You may stop taking the pill whenever you wish. Consider a visit with your healthcare provider for a pre-pregnancy checkup before you stop taking the pill.

What should I know about my period when taking Previfem[®]?

Your periods may be lighter and shorter than usual. Some women may miss a period. Irregular vaginal bleeding or spotting may happen while you are taking Previfem[®] especially during the first few months of use. This usually is not a serious problem. It is important to continue taking your pills on a regular schedule to prevent a pregnancy.

What are the ingredients in Previfem[®]?

Active ingredients: Each blue pill contains norgestimate and ethinyl estradiol.

Inactive ingredients:

Blue pills: crospovidone, FD & C Blue No.2 Aluminum Lake, lactose anhydrous, magnesium stearate, and pregelatinized starch.

Green pills: crospovidone, D & C Yellow No.10 Aluminum Lake, FD & C Blue No.2 Aluminum Lake, lactose anhydrous, magnesium stearate, and pregelatinized starch.

Instructions For Use Previfem[®] (norgestimate and ethinyl estradiol tablets, USP)

Important Information about taking Previfem[®]:

- Take 1 pill every day at the same time. Take the pills in the order directed on your blister pack.
- Do not skip your pills, even if you do not have sex often. If you miss pills (including starting the blister pack late) **you could get pregnant.** The more pills you miss, the more likely you are to get pregnant.
- If you have trouble remembering to take Previfem[®], talk to your healthcare provider. When you first start taking Previfem[®], spotting or light bleeding in between your periods may occur. Contact your healthcare provider if this does not go away after a few months.
- You may feel sick to your stomach (nauseous), especially during the first few months of taking Previfem[®]. If you feel sick to your stomach, do not stop taking the pill. The problem will usually go away. If your nausea does not go away, call your healthcare provider.
- Missing pills can also cause spotting or light bleeding, even when you take the missed pills later. On the days you take 2 pills to make up for missed pills (see **What should I do if I miss any Previfem[®] pills?** below), you could also feel a little sick to your stomach.
- It is not uncommon to miss a period. However, if you miss a period and have not taken Previfem[®] according to directions, or miss 2 periods in a row, or feel like you may be pregnant, call your healthcare provider. If you have a positive pregnancy test, you should stop taking Previfem[®].
- If you have vomiting or diarrhea within 3 to 4 hours of taking your pill, take another pill of the same color from your extra pill blister pack. If you do not have an extra pill blister pack, take the next pill in your pill blister pack. Continue taking all your remaining pills in order. Start the first pill of your next pill blister pack the day after finishing your current pill blister pack. This will be 1 day earlier than originally scheduled. Continue on your new schedule.
- If you have vomiting or diarrhea for more than 1 day, your birth control pills may not work as well. Use an additional birth control method, like condoms and a spermicide, until you check with your healthcare provider.
- Stop taking Previfem[®] at least 4 weeks before you have major surgery and do not restart after the surgery without asking your healthcare provider. Be sure to use other forms of contraception (like condoms and spermicide) during this time period.

Before you start taking Previfem[®]:

- Decide what time of day you want to take your pill. It is important to take it at the same time every day and in the order as directed on your blister pack.
- Have backup contraception (condoms and spermicide) available and if possible, an extra full blister pack of pills as needed.

When should I start taking Previfem[®]?

If you start taking Previfem[®] and you have not used a hormonal birth control method before:

- There are 2 ways to start taking your birth control pills. You can either start on a Sunday (Sunday Start) or on the first day (Day 1) of your natural menstrual period (Day 1 Start). Your healthcare provider should tell you when to start taking your birth control pill.
- If you use the Sunday Start, use non-hormonal back-up contraception such as condoms and spermicide for the first 7 days that you take Previfem[®]. You do not need back-up contraception if you use the Day 1 Start.

If you start taking Previfem[®] and you are switching from another birth control pill:

- Start your new Previfem[®] pack on the same day that you would start the next pack of your previous birth control method.
- Do not continue taking the pills from your previous birth control pack.

If you start taking Previfem[®] and previously used a vaginal ring or transdermal patch:

- Start using Previfem[®] on the day you would have reapplied the next ring or patch.

If you start taking Previfem[®] and you are switching from a progestin-only method such as an implant or injection:

- Start taking Previfem[®] on the day of removal of your implant or on the day when you would have had your next injection.

If you start taking Previfem[®] and you are switching from an intrauterine device or system (IUD or IUS):

- Start taking Previfem[®] on the day of removal of your IUD or IUS.
- You do not need back-up contraception if your IUD or IUS is removed on the first day (Day 1) of your period. If your IUD or IUS is removed on any other day, use non-hormonal back-up contraception such as condoms and spermicide for the first 7 days that you take Previfem[®].

Keep a calendar to track your period:

If this is the first time you are taking birth control pills, read, **"When should I start taking Previfem[®]?"** above.

Follow these instructions for either a **Sunday Start** or a **Day 1 Start**.

Sunday Start:

You will use a **Sunday Start** if your healthcare provider told you to take your first pill on a Sunday.

- Take pill 1 on the Sunday **after your period starts**.
- If your period starts on a Sunday, take pill "1" that day and refer to Day 1 Start instructions below.
- Take 1 pill every day in the order on the blister pack at the same time each day for 28 days.
- After taking the last pill on Day 28 from the blister pack, start taking the first pill from a new blister pack, on the same day of the week as the first blister pack (Sunday). Take the first pill in the new pack whether or not you are having your period.
- Use non-hormonal back-up contraception such as condoms and spermicide for the first 7 days of the first cycle that you take Previfem[®].

Day 1 Start:

You will use a **Day 1 Start** if your doctor told you to take your first pill (Day 1) on the **first day of your period**.

- Take 1 pill every day in the order of the blister pack, at the same time each day, for 28 days.
- After taking the last pill on Day 28 from the blister pack, start taking the first pill from a new pack, on the same day of the week as the first pack. Take the first pill in the new pack whether or not you are having your period.

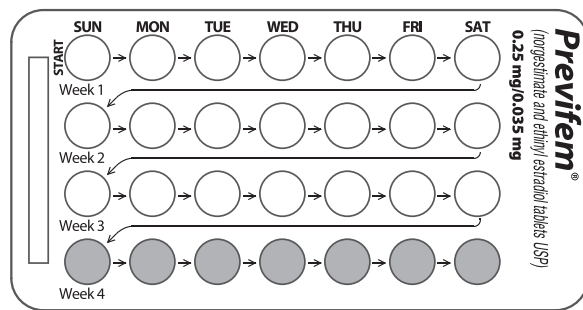
Previfem[®] comes in a blister pack. Read the instructions below for using your blister pack.

BEFORE YOU START TAKING YOUR PILLS:

- BE SURE TO READ THESE DIRECTIONS:** Before you start taking your pills. Anytime you are not sure what to do.
- THE RIGHT WAY TO TAKE THE PILL IS TO TAKE ONE PILL EVERY DAY AT THE SAME TIME.** If you miss pills you could get pregnant. This includes starting the pack late. The more pills you miss, the more likely you are to get pregnant.
- MANY WOMEN HAVE SPOTTING OR LIGHT BLEEDING, OR MAY FEEL SICK TO THEIR STOMACH DURING THE FIRST 1 TO 3 PACKS OF PILLS.** If you feel sick to your stomach or have spotting or light bleeding, do not stop taking the pill. The problem will usually go away. If it doesn't go away, check with your healthcare professional.
- MISSING PILLS CAN ALSO CAUSE SPOTTING OR LIGHT BLEEDING,** even when you make up these missed pills. On the days you take 2 pills to make up for missed pills, you could also feel a little sick to your stomach.
- IF YOU HAVE VOMITING OR DIARRHEA, OR IF YOU TAKE SOME MEDICINES,** your pills may not work as well. Use a back-up method (such as a condom or spermicide) until you check with your healthcare professional.
- IF YOU HAVE TROUBLE REMEMBERING TO TAKE THE PILL,** talk to your healthcare professional about how to make pill-taking easier or about using another method of birth control.
- IF YOU HAVE ANY QUESTIONS OR ARE UNSURE ABOUT THE INFORMATION IN THIS LEAFLET,** call your healthcare professional.

BEFORE YOU START TAKING YOUR PILLS

- DECIDE WHAT TIME OF DAY YOU WANT TO TAKE YOUR PILL.** It is important to take it at about the same time every day.
- LOOK AT YOUR PILL PACK** The pill pack has 21 active pills (with hormones) to take for 3 weeks. This is followed by 1 week of reminder green pills (without hormones). There are 21 blue active pills, and 7 green reminder pills.
- ALSO FIND:**
 - where on the pack to start taking pills,
 - in what order to take the pills (follow the arrows),
 - the week numbers as shown in the diagram below.



4. BE SURE YOU HAVE READY AT ALL TIMES:

- ANOTHER KIND OF BIRTH CONTROL** (such as a condom or spermicide) to use as a back-up method in case you miss pills.
- AN EXTRA, FULL PILL PACK.**

What should I do if I miss any Previfem[®] pills?

If you miss 1 pill in Weeks 1, 2, or 3, follow these steps:

- Take it as soon as you remember. Take the next pill at your regular time.
- This means you may take 2 pills in 1 day.
- Then continue taking 1 pill every day until you finish the pack.
- You do not need to use a back-up birth control method if you have sex.

If you miss 2 pills in Week 1 or Week 2 of your pack, follow these steps:

- Take the 2 missed pills as soon as possible and the next 2 pills the next day.
- Then continue to take 1 pill every day until you finish the pack.
- Use a non-hormonal birth control method (such as a condom and spermicide) as a back-up if you have sex during the first 7 days after missing your pills.

If you miss 2 pills in a row in Week 3, or you miss 3 or more pills in a row during Weeks 1, 2, or 3 of the pack, follow these steps:

- If you are a Day 1 Starter:**
 - Throw out the rest of the pill pack and start a new pack that same day.
 - You may not have your period this month but this is expected. However, if you miss your period 2 months in a row, call your healthcare provider because you might be pregnant.

- You could become pregnant if you have sex during the first 7 days after you restart your pills. You MUST use a non-hormonal birth control method (such as a condom and spermicide) as a back-up if you have sex during the first 7 days after you restart your pills.

• If you are a Sunday Starter:

- Keep taking 1 pill every day until Sunday. On Sunday, throw out the rest of the pack and start a new pack of pills that same day.
- Use a non-hormonal birth control method (such as a condom and spermicide) as a back-up if you have sex during the first 7 days after you restart your pills.

If you have any questions or are unsure about the information in this leaflet, call your healthcare provider.

This Patient Information and Instructions for Use has been approved by the U.S. Food and Drug Administration.

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