HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use LO/OVRAL safely and effectively. See full prescribing information for LO/OVRAL.

LO/OVRAL® (norgestrel and ethinyl estradiol tablets) for oral use
Initial U.S. Approval: 1979

WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS
See Full Prescribing Information for complete boxed warning.

LO/OVRAL is 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----------
Warnings and Precautions (5.10) 04/2022

----------INDICATIONS AND USAGE----------
LO/OVRAL is a progestin/estrogen COC indicated for use by females of reproductive potential to prevent pregnancy. (1) The efficacy of LO/OVRAL in women with a body mass index (BMI) of > 35 kg/m^2 has not been evaluated. (1, 8.8)

----------DOSAGE AND ADMINISTRATION----------
- Take one tablet by mouth at the same time every day for 21 days. (2.1)
- Take tablets in the order directed on the blister pack. (2.1)

----------DOSAGE FORMS AND STRENGTHS----------
LO/OVRAL consists of 21 tablets in the following order (3):
- 21 white tablets (active), each containing 0.3 mg norgestrel and 0.03 mg ethinyl estradiol.

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

----------WARNINGS AND PRECAUTIONS----------
- Thrombotic Disorders and Other Vascular Problems: Stop LO/OVRAL if a thrombotic event occurs. Stop at least 4 weeks before 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 LO/OVRAL if jaundice occurs. (5.2)
- High blood pressure: If used in women with well-controlled hypertension, monitor blood pressure and stop LO/OVRAL if blood pressure rises significantly. (5.4)
- Carbohydrate and lipid metabolic effects: Monitor prediabetic and diabetic women taking LO/OVRAL. Consider an alternative contraceptive method for women with uncontrolled dyslipidemia. (5.6)
- Headache: Evaluate significant change in headaches and discontinue LO/OVRAL if indicated. (5.7)
- Bleeding Irregularities and Amenorrhea: Evaluate irregular bleeding or amenorrhea. (5.8)

----------ADVERSE REACTIONS----------
The most common adverse reactions (≥ 2%) were: headache, nausea, acne, vaginal infection, vaginal discharge, dysmenorrhea, breast discomfort, depression, increased appetite, gastrointestinal symptoms, nervousness, backache, change in menstrual flow, chloasma/melasma, and exacerbation of varicose veins. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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

----------USE IN SPECIFIC POPULATIONS----------
- Lactation: Advise use of another contraceptive method. LO/OVRAL can decrease milk production. (8.2)

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

Revised: 10/2022

FULL PRESCRIBING INFORMATION
WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS

* Sections or subsections omitted from the full prescribing information are not listed.

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 should not be used by women who are over 35 years of age and smoke *[see Contraindications (4)]*.

1 INDICATIONS AND USAGE

LO/OVRAL is indicated for use by females of reproductive potential to prevent pregnancy.

The efficacy of LO/OVRAL in women with a body mass index (BMI) of > 35 kg/m^2 has not been evaluated.

2 DOSAGE AND ADMINISTRATION

2.1 How to Start LO/OVRAL

LO/OVRAL is dispensed in a blister pack *[see How Supplied/Storage and Handling (16)]*. LO/OVRAL 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.

2.2 How to Take LO/OVRAL-

Table 1: Instructions for Administration of LO/OVRAL

<table>
<tr>
<td rowspan="2">Starting combined oral contraceptive (COC) in women not currently using hormonal contraception (Day 1 Start or Sunday Start)
Important:
Consider the possibility of ovulation and conception prior to initiation of this product.
Tablet Color:
Lo/Ovral active tablets are white (Day 1 to Day 21).</td>
<td>Day 1 Start:
• Take first white active tablet without regard to meals on the first day of menses.
• Take subsequent white active tablets once daily at the same time each day for a total of 21 days.
• After taking the 21 tablets in the dispenser, the tablets are discontinued for one week (the next 7 days).
• After 7 days, begin taking the next tablet pack.
• Begin each subsequent pack on the same day of the week as the first cycle pack (i.e., 7 days after taking the last tablet).</td>
</tr>
<tr>
<td>Sunday Start:
• Take the first white active tablet on the first Sunday after the onset of menses.
• Use additional non-hormonal contraception (such as condoms or spermicide) for the first 7 days of product use.
• Take subsequent white active tablets once daily at the same time each day for a total of 21 days.
• After taking the 21 tablets in the dispenser, the tablets are discontinued for one week (the next 7 days).
• After 7 days, begin taking the next tablet pack.
• Begin each subsequent pack on the same day of the week as the first cycle pack (i.e., 7 days after taking the last tablet).</td>
</tr>
</table>

Switching to Lo/Ovral from another oral contraceptive	• Start Lo/Ovral on the day when the new pack of the previous oral contraceptive was taken. • When switching from a progestin-only pill, Lo/Ovral should be started the next day and a non-hormonal contraceptive (such as condoms or spermicide) should be used for the first 7 days of product use.
Switching from another contraceptive method to Lo/Ovral	**Start Lo/Ovral:**
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. • Use additional non-hormonal contraception (such as condoms or spermicide) for the first 7 days of product use. if starting LATER than the next injection is due.
Intrauterine contraceptive	• On the day of removal • Use additional non-hormonal contraception (such as condoms or spermicide) for the first 7 days of product use if the IUD is not removed on first day of the patient's menstrual cycle.
Implant	• On the day of removal. • Use additional non-hormonal contraception (such as condoms or spermicide) for the first 7 days of product use if starting at a date after removal of implant.

Starting LO/OVRAL after Abortion or Miscarriage

First-trimester

After a first-trimester abortion or miscarriage, LO/OVRAL may be started immediately. An additional method of contraception is not needed if LO/OVRAL is started within 5 days after termination of pregnancy.

If LO/OVRAL is not started within 5 days after termination of the pregnancy, the patient should use additional non-hormonal contraception (such as condoms or spermicide) for the first 7 days of her first pack of LO/OVRAL.

Second-trimester

Do not start until 4 weeks after a second-trimester abortion or miscarriage, due to the increased risk of thromboembolic disease. Start LO/OVRAL following the instructions in Table 1 for Sunday Start, as desired. If using Sunday Start, use additional non-hormonal contraception (such as condoms or spermicide) for the first 7 days of the patient's first pack of LO/OVRAL *[see Contraindications (4), Warnings and Precautions (5.1).*

Starting LO/OVRAL after Childbirth

Do not start until 4 weeks after delivery, due to the increased risk of thromboembolic disease. Start contraceptive therapy with LO/OVRAL following the instructions in Table 1 for women not currently using hormonal contraception.

If the woman has not yet had a period postpartum, consider the possibility of ovulation and conception occurring prior to use of LO/OVRAL *[see Contraindications (4), Warnings and Precautions (5.1), Use in Specific Populations (8.1 Pregnancy)*.

2.3 Missed Tablets

Table 2: Instructions for Missed Lo/Ovral Tablets

• If one **white active** tablet is missed in Weeks 1, 2 or 3	Take the tablet as soon as possible. Continue taking one tablet a day until the pack is finished.
• If two **white 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 pack is finished. Use additional non-hormonal contraception (such as condoms or spermicide) for the following 7 days**.**
• If two **white active** tablets are missed in Week 3 or three or more consecutive **white active** tablets are missed in a row in Weeks 1, 2 or 3	**Day 1 Start:** Throw out the rest of the 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 pack and start a new pack that same day. Use additional non-hormonal contraception (such as condoms or spermicide) for the following 7 days.

2.4 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 a white active tablet, handle this as a missed tablet *[see Dosage and Administration (2.3)]*.

3 DOSAGE FORMS AND STRENGTHS

LO/OVRAL (norgestrel and ethinyl estradiol tablets) is available in blister packs.

Each blister pack (21 tablets) contains in the following order:
21 white, round (active) tablets imprinted with “78 on one side and “Wyeth” on the other and each containing 0.3 mg norgestrel and 0.03 mg ethinyl estradiol.

4 CONTRAINDICATIONS

LO/OVRAL is contraindicated in females who develop or 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 have 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 Use in Specific Populations (8.1)]*
- Current diagnosis of, or history of, breast cancer, which may be hormone-sensitive [see Warnings *and Precautions (5.10)]*
- Are receiving 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)*].

5 WARNINGS AND PRECAUTIONS

5.1 Thrombotic Disorders and Other Vascular Problems

Stop LO/OVRAL if an arterial thrombotic event or venous thromboembolic (VTE) event occurs.

Stop LO/OVRAL if there is unexplained loss of vision, proptosis, diplopia, papilledema. Evaluate for retinal vein thrombosis immediately *[see Adverse Reactions (6.2)].*

If feasible, stop LO/OVRAL 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 LO/OVRAL 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.

The use of COCs increases the risk of VTE. However, pregnancy increases the risk of VTE as much or more than the use of COCs. The risk of VTE in women using COCs is 3 to 9 cases per 10,000 woman-years. The risk of VTE is highest during the first year of use of a COCs and when restarting oral contraception after a break of 4 weeks or longer. The risk of thromboembolic disease due to COCs gradually disappears after COC use is discontinued.

Use of COCs also increases the risk of arterial thromboses that result in strokes and myocardial infarctions, especially in women with other risk factors for these events. COCs have been shown to increase both the relative and attributable risks of cerebrovascular events (thrombotic and hemorrhagic strokes). This risk increases with age, particularly in women over 35 years of age who smoke.

Use COCs with caution in women with cardiovascular disease risk factors *[see Contraindications (4)]*.

5.2 Liver Disease

Impaired Liver Function

Do not use LO/OVRAL 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 LO/OVRAL if jaundice develops.

Liver Tumors

LO/OVRAL 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 per 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.

5.3 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 subjects using ethinyl estradiol-containing medications such as COCs. Discontinue Lo/Ovral prior to starting therapy with the combination drug regimen ombitasvir/paritaprevir/ritonavir, with or without dasabuvir [see *Contraindications (4)*]. Lo/Ovral can be restarted approximately 2 weeks following completion of treatment with the combination drug regimen.

5.4 High Blood Pressure

LO/OVRAL 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 LO/OVRAL 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.

5.5 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 cholestasis predicts an increased risk with subsequent COC use. Women with a history of pregnancy-related cholestasis may be at an increased risk for COC related cholestasis.

5.6 Carbohydrate and Lipid Metabolic Effect

Carefully monitor prediabetic and diabetic women who are taking LO/OVRAL. COCs may decrease glucose tolerance.

Consider alternative contraception for women with uncontrolled dyslipidemias. 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.

5.7 Headache

If a woman taking LO/OVRAL develops new headaches that are recurrent, persistent, or severe, evaluate the cause and discontinue LO/OVRAL if indicated.

Consider discontinuation of LO/OVRAL in the case of increased frequency or severity of migraine during COC use (which may be prodromal of a cerebrovascular event) *[see Contraindications (4)]*.

5.8 Bleeding Irregularities and Amenorrhea

Unscheduled Bleeding and Spotting

Unscheduled (breakthrough or intracyclic) 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.

The frequency and duration of unscheduled bleeding and/or spotting was assessed in 1,343 subjects across nine studies. Unscheduled bleeding and spotting occurred in 15% of women in the first cycle on treatment, 9% in Cycle 3, 5% in Cycle 6, 5% in Cycle 9 and 5% in Cycle 12. In 1287 subjects, LO/OVRAL was discontinued in 1% of subjects due to breakthrough bleeding and 1% of subjects discontinued due to spotting.

Amenorrhea and Oligomenorrhea

Women who use LO/OVRAL may experience amenorrhea, absence of withdrawal bleeding, even if they are not pregnant. In the clinical trials with LO/OVRAL, amenorrhea was reported in 3% of subjects in the first cycle, 2% in Cycle 3, 2% in Cycle 6, 1% in Cycle 9 and 2% in Cycle 12. Amenorrhea was the reason for study discontinuation in < 1% of subjects.

Some women may experience amenorrhea or oligomenorrhea after discontinuation of COCs, especially when such a condition was preexistent.

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 Depression

Carefully observe women with a history of depression and discontinue LO/OVRAL if depression recurs to a serious degree.

5.10 Malignant Neoplasms

Breast Cancer

Lo/Ovral is contraindicated in women who currently have or have had breast cancer because breast cancer may be hormonally sensitive *[see Contraindications (4)]*.

Epidemiology studies have not found a consistent association between use of combined oral contraceptives (COCs) and breast cancer risk. Studies do not show an association between ever (current or past) use of COCs and risk of breast cancer. However, some studies report a small increase in the risk of breast cancer among current or recent users (<6 months since last use) and current users with longer duration of COC use. [see *Postmarketing Experience* (*6.2*)].

Cervical Cancer

Some studies suggest that COCs are associated with an increase in the risk of cervical cancer or intraepithelial neoplasia. However, there is controversy about the extent to which these findings may be due to differences in sexual behavior and other factors.

5.11 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.

5.12 Hereditary Angioedema

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

5.13 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 LO/OVRAL.

6 ADVERSE REACTIONS

The following serious adverse reactions with the use of COCs are discussed elsewhere in the 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)]*

The following adverse reactions are commonly reported by COC users. Because these reactions are voluntarily reported by from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure:

Irregular uterine bleeding

Nausea

Breast tenderness

Headache

6.1 Clinical Trial Experience

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

The safety of LO/OVRAL was evaluated in nine clinical investigations with a cumulative total of 1,343 subjects aged 15 to 40 and followed for a total of 11,085 cycles (852 women years of study). The subjects were recruited from a wide geographical distribution in the United States and including all socio-economic groups. The ethnic distribution of study volunteers was: 69% white; 28% black; 1.0% Asian; and 2% other backgrounds. 28% nulligravidas and 72% gravidas.

Common Adverse Reactions (≥ 2% of all subjects): The most common adverse reactions were headache (6%), nausea (5%), acne (4%), vaginal infection (4%), vaginal discharge (4%), dysmenorrhea (4%) breast discomfort (3%), depression (3%), increased appetite (3%), gastrointestinal symptoms (3%), nervousness (3%), backache (2%), change in menstrual flow (2%), chloasma/melasma (2%), exacerbation of varicose veins (2%).

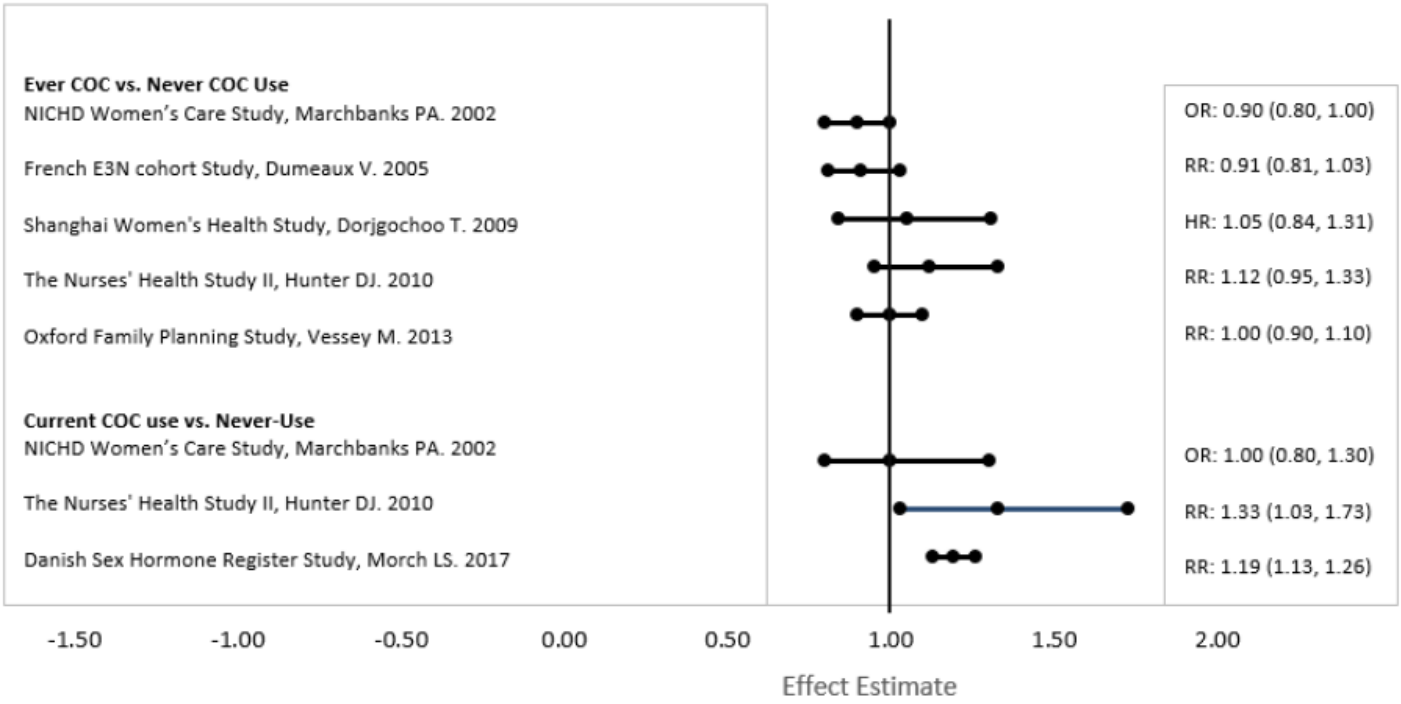
Adverse Reactions Leading to Study Discontinuation: A total of 103 subjects (8%) dropped out of the trials due to adverse reactions, including unscheduled bleeding (breakthrough bleeding 1%; spotting 1%), and the following each in < 1%, headache including migraine, amenorrhea, nausea, acne, change in menstrual flow, nervousness, increase in weight, depression, and high blood pressure.

6.2 Postmarketing Experience

Five studies that compared breast cancer risk between ever-users (current or past use) of COCs and never-users of COCs reported no association between ever use of COCs and breast cancer risk, with effect estimates ranging from 0.90 - 1.12 (Figure 1).

Three studies compared breast cancer risk between current or recent COC users (<6 months since last use) and never users of COCs (Figure 1). One of these studies reported no association between breast cancer risk and COC use. The other two studies found an increased relative risk of 1.19 - 1.33 with current or recent use. Both of these studies found an increased risk of breast cancer with current use of longer duration, with relative risks ranging from 1.03 with less than one year of COC use to approximately 1.4 with more than 8-10 years of COC use.

Figure 1: Relevant Studies of Risk of Breast Cancer with Combined Oral Contraceptives



RR = relative risk; OR = odds ratio; HR = hazard ratio. "ever COC" are females with current or past COC use; "never COC use" are females that never used COCs.

The following adverse reactions have been identified during post approval use of LO/OVRAL. Because these reactions are reported voluntarily from a population of uncertain size, it is difficult to reliably estimate their frequency or evaluate a causal relationship to drug exposure.

Arterial events: myocardial infarction,arterial thromboembolism, and cerebral hemorrhage.

Eye disorders: retinal vein thrombosis, change in corneal curvature (steepening).

GI disorders: nausea, pancreatitis.

Hepatobiliary disorders: gallbladder disease and cholestatic jaundice.

Immune system disorders: anaphylactic/anaphylactoid reactions, including urticaria, angioedema, and severe reactions with respiratory and circulatory symptoms.

Metabolism and nutrition disorders: change in weight or appetite (increase or decrease), carbohydrate and lipid effects.

Neoplasms, Benign, Malignant, and Unspecified: Carincoma of the reproductive organs and breasts, Hepatic neoplasia (including hapatic adenomas, or benign liver tumors).

Skin and subcutaneous disorders: hirsutism, erythema multiforme, erythema nodosum, hemorrhagic eruption, and melasma/chloasma, which may persist

Nervous system disorders: headache, migraine.

Psychiatric disorders: mood swings.

Reproductive system and breast disorders: breast changes (tenderness, pain, enlargement, and secretion), premenstrual syndrome.

Vascular disorders: venous thrombosis, pulmonary embolism, cerebral thrombosis, mesenteric thrombois, and retinal vascular thrombosis.

7 DRUG INTERACTIONS

Consult the labeling of concurrently used drugs to obtain further information about interactions with hormonal contraceptives or the potential for enzyme alterations.

7.1 Effects of Other Drugs on Combined Oral Contraceptives

Substances decreasing the plasma concentrations of COCs and potentially diminishing the efficacy of COCs:

Drugs or herbal products that induce certain enzymes, including cytochrome P450 3A4 (CYP3A4), may decrease the plasma concentrations of COCs and potentially diminish the effectiveness of COCs or increase breakthrough bleeding. Some drugs or herbal products that may decrease the effectiveness of oral contraceptives including phenytoin, barbiturates, carbamazepine, bosentan, felbamate, griseofulvin, oxcarbazepine, rifampicin, topiramate, rifabutin, rufinamide, aprepitant, and products containing St. John's wort. Interactions between COCs and other drugs may lead to breakthrough bleeding and/or contraceptive failure. Counsel women to use an alternative non-hormonal method of contraception or a back-up method when enzyme inducers are used with COCs, and to continue back-up non-hormonal contraception for 28 days after discontinuing the enzyme inducer to ensure contraceptive reliability.

Colesevelam: Colesevelam, a bile acid sequestrant, given together with a COC, has been shown to significantly decrease the AUC of EE. The drug interaction between the contraceptive and colesevelam was decreased when the two drug products were given 4 hours apart.

Substances increasing the plasma concentrations of COCs:

Co-administration of atorvastatin or rosuvastatin and certain COCs containing ethinyl estradiol (EE) increase AUC values for EE by approximately 20 to 25%. Ascorbic acid and acetaminophen may increase plasma EE concentrations, possibly by inhibition of conjugation. Concomitant administration of CYP3A4 inhibitors such as itraconazole, voriconazole, fluconazole, grapefruit juice, or ketoconazole may increase plasma hormone concentrations.

Human immunodeficiency virus (HIV)/Hepatitis C virus (HCV) protease inhibitors and non-nucleoside reverse transcriptase inhibitors:

Significant changes (increase or decrease) in the plasma concentrations of estrogen and/or progestin have been noted in some cases of co-administration with HIV protease inhibitors (decrease [e.g., nelfinavir, ritonavir, darunavir/ritonavir, (fos)amprenavir/ritonavir, lopinavir/ritonavir, and tipranavir/ritonavir] or increase [e.g., indinavir and atazanavir/ritonavir])/HCV protease inhibitors or with non-nucleoside reverse transcriptase inhibitors (decrease [e.g., nevirapine and efavirenz] or increase [e.g., etravirine]). These changes may be clinically relevant in some cases.

7.2 Concomitant Use with HCV Combination Therapy – Liver Enzyme Elevation

Do not co-administer Lo/Ovral with HCV drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, due to potential for ALT elevations [see *Warnings and Precautions (5.3)*].

7.3 Effects of Combined Oral Contraceptives on Other Drugs

COCs containing EE may inhibit the metabolism of other compounds (e.g., cyclosporine, prednisolone, theophylline, tizanidine, and voriconazole) and increase their plasma concentrations. COCs have been shown to decrease plasma concentrations of acetaminophen, clofibric acid, morphine, salicylic acid, and temazepam. A significant decrease in plasma concentration of lamotrigine has been shown, likely due to induction of lamotrigine glucuronidation. This may reduce seizure control; therefore, dosage adjustments of lamotrigine may be necessary.

Women on thyroid hormone replacement therapy may need increased doses of thyroid hormone because the serum concentration of thyroid-binding globulin increases with use of COCs *[see Warnings and Precautions (5.11)]*.

7.4 Interactions with Laboratory Tests

The use of contraceptive steroids may influence the results of certain laboratory tests, such as coagulation factors, lipids, glucose tolerance, and binding proteins.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There is little or no increased risk of birth defects in the children of females who inadvertently use COCs during early pregnancy. Animal data, along with epidemiologic studies, do not show an increased risk of birth defects with use of COCs prior to pregnancy or during early pregnancy.

Discontinue Lo/Ovral use if pregnancy is confirmed.

Do not administer COCs to induce withdrawal bleeding as a test for pregnancy. Do not use COCs during pregnancy to treat threatened or habitual abortion.

Animal Data

Several studies were conducted in rodents and rabbits to evaluate the potential reproductive toxicity of Norgestrel in combination with Ethinyl Estradiol (Norgestrel/EE) during pregnancy or lactation at doses approximately up to 25-fold over the clinical dose.

In rats administered Norgestrel/EE from Day 8-21 of gestation, there were no maternal adverse effects and no effects on embryofetal development or reproductive potential of the offspring. In rabbits, Norgestrel/EE administered from Day 8-18 of gestation showed a decrease in maternal body weight gain and litter size. There was no indication of teratogenicity in either rats or rabbits.

Administration of Norgestrel/EE in mice and rats to suppress fertility was followed by a recovery of reproductive function and fertility. In lactating female rats administered Norgestrel/EE at doses up to 25-fold the clinical dose from delivery to 21 days post-delivery or weaning, there were no adverse maternal effects, no effect on the lactation process, and no effect on offspring growth.

8.2 Lactation

Risk Summary

Contraceptive hormones and/or metabolites are present in human milk in small amounts. The effects of Lo/Ovral on the breastfed child is unknown. COCs can reduce milk production in lactating women. Advise the nursing mother to use a non-COC contraception, when possible, until she has weaned her child. This is less likely to occur once breastfeeding is well-established; however, it can occur at any time in some women. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Lo/Ovral and any potential adverse effects on the breast-fed child from Lo-Ovral or from the underlying maternal condition.

8.4 Pediatric Use

Safety and efficacy of LO/OVRAL have been established in women of reproductive age. Efficacy is expected to be the same in postpubertal adolescents under the age of 18 years as for users 18 years and older. Use of this LO/OVRAL before menarche is not indicated.

8.5 Geriatric Use

LO/OVRAL has not been studied in postmenopausal women and is not indicated in this population.

8.6 Hepatic Impairment

The pharmacokinetics of LO/OVRAL has not been studied in subjects with hepatic impairment. However, steroid hormones may be poorly metabolized in patients with hepatic impairment. 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 *[see Contraindications (4) and Warnings and Precautions (5.2)]*.

8.7 Renal Impairment

The pharmacokinetics of LO/OVRAL has not been studied in women with renal impairment.

8.8 Body Mass Index

The safety and efficacy of LO/OVRAL in women with a body mass index (BMI) > 35 kg/m^2 has not been evaluated *[see Clinical Studies (14)]*.

10 OVERDOSAGE

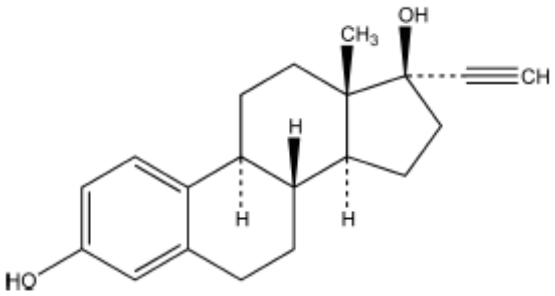
There have been no reports of serious ill effects from overdose of oral contraceptives, including ingestion by children. Overdosage may cause withdrawal bleeding in females and nausea.

11 DESCRIPTION

LO/OVRAL is a combination oral contraceptive for oral administration consisting of active white tablets containing norgestrel, a progestin, and ethinyl estradiol, an estrogen.

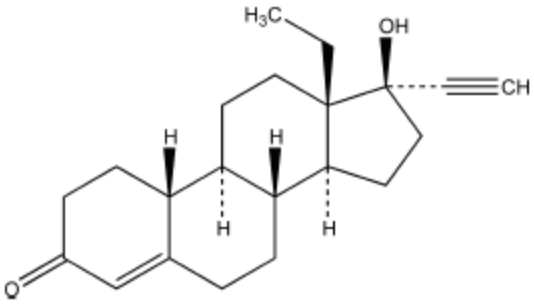
Each active white tablet contains 0.3 mg norgestrel and 0.03 mg ethinyl estradiol. Inactive ingredients include lactose monohydrate, magnesium stearate, microcrystalline cellulose, and polacrilin potassium.

The chemical name of ethinyl estradiol is 19-Norpregna-1,3,5(10)-trien-20-yne-3,17-diol, (17α)-. The empirical formula of ethinyl estradiol is $C_{20}H_{24}O_2$ and the structural formula is:



Ethinyl Estradiol
M.W. 296.40

The chemical name of norgestrel is 18, 19-Dinorpregn-4-en-20-yn-3-one, 13-ethyl-17-hydroxy-, (17α)-(±)-, a totally synthetic progesterone. The empirical formula of norgestrel is $C_{21}H_{28}O_2$ and the structural formula is:



Norgestrel
M.W.312.45

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

COCs lower the risk of becoming pregnant primarily by suppressing ovulation. Other possible mechanisms may include cervical mucus changes that inhibit sperm penetration and endometrial changes that reduce the likelihood of implantation.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

[See Warnings and Precautions (5.10) and Use in Specific Populations (8.1).]

14 CLINICAL STUDIES

Nine clinical trials in different parts of the United States recruited subjects aged 15 to 40. A total of 1,287 subjects completed at least one cycle, 1,062 three cycles, 766 six cycles, 429 twelve cycles, and 244 fifteen cycles, making a total of 11,085 cycles (852 women-years of study). The racial demographic of subjects LO/OVRAL was: 69% Caucasian, 28% African-American, 1% Asian and < 1% Native American.

The pregnancy rate was approximately 1 pregnancy per 100 women-years of use.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

LO/OVRAL® (norgestrel and ethinyl estradiol tablets) is available in cartons of 100 blister packs containing 21 tablets:

NDC 0080-2526-01 Cartons of 100 blister packs

Each blister pack (21 tablets) contains in the following order:

21 white, round (active) tablets imprinted with “78” on one side and “Wyeth” on the other and each containing 0.3 mg norgestrel and 0.03 mg ethinyl estradiol.

16.2 Storage Conditions

Store at controlled room temperature 20º to 25ºC (68ºF to 77º F); excursions permitted from 15ºC to 30ºC (59ºF to 86ºF) *[see USP Controlled Room Temperature]*.

Protect from light.

Keep this drug and all drugs out of the reach of children.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the 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)]*.

LO/OVRAL does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

LO/OVRAL is not to be used during pregnancy; if pregnancy occurs during use of LO/OVRAL instruct the patient to stop further use *[see Specific Populations (8.1)]*.

Take one tablet daily by mouth at the same time every day. Instruct patients what to do in the event pills are missed *[see Dosage and Administration (2.2)]*.

Use a back-up or alternative method of contraception when enzyme inducers are used with LO/OVRAL *[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 (8.2)]*.

Women who start COCs postpartum, and who have not yet had a period, should use an additional method of contraception until she has taken a white 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 if amenorrhea persists beyond two consecutive cycles *[see Warnings and Precautions (5.8)]*.

PATIENT INFORMATION

LO/OVRAL *[Low-O-Vral]*

(norgestrel and ethinyl estradiol tablets)

What is the most important information I should know about LO/OVRAL?

Do not use LO/OVRAL 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 LO/OVRAL?

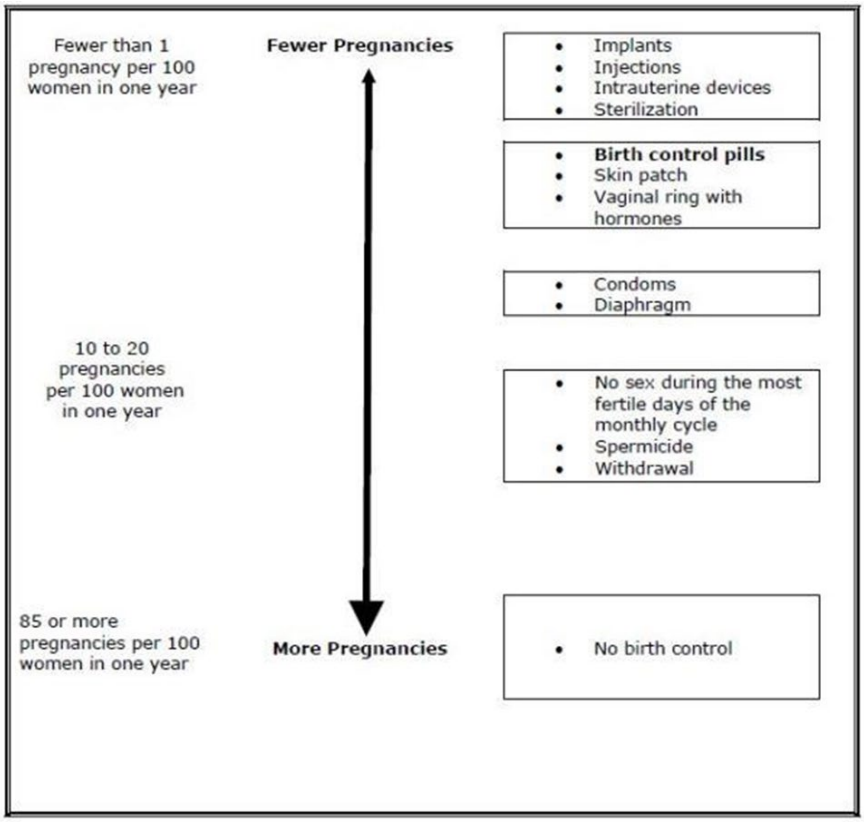
LO/OVRAL is a birth control pill (oral hormonal contraceptive) used by women to prevent pregnancy.

How does LO/OVRAL 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 from the clinical study, about 1 to 4 out of 100 subjects may get pregnant during the first year they use LO/OVRAL.

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 LO/OVRAL?

Do not take LO/OVRAL 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
- have or had breast cancer

If any of these conditions happen while you are taking LO/OVRAL, stop taking LO/OVRAL right away and talk to your healthcare provider. Use non-hormonal contraception (such as condoms or spermicide) when you stop taking LO/OVRAL.

What should I tell my healthcare provider before taking LO/OVRAL?

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. LO/OVRAL may decrease the amount of breast milk you make. A small amount of the hormones in LO/OVRAL 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.

LO/OVRAL may affect the way other medicines work, and other medicines may affect how well LO/OVRAL 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 LO/OVRAL?

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

What are the possible serious side effects of LO/OVRAL?

Like pregnancy, LO/OVRAL 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 smoke, are obese, or are older than 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
- sudden severe shortness of breath
- sudden change in vision or blindness
- chest pain
- a sudden, severe headache unlike your usual headaches
- weakness or numbness in your arm or leg
- trouble speaking

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**
- **gallbladder problems**
- **changes in the sugar and fat (cholesterol and triglycerides) levels in your blood**
- **new or worsening headaches including migraine headaches**
- **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 is 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 LO/OVRAL. Use sunscreen if you have to be in the sunlight.

What are the most common side effects of LO/OVRAL?

- headache
- nausea
- acne
- vaginal infections/discharge
- menstrual cramps
- breast tenderness
- depression
- increased appetite
- stomach discomfort
- nervousness
- backache
- irregular uterine bleeding

- skin discoloration
- worsening varicose veins

These are not all the possible side effects of LO/OVRAL. For more information, ask your healthcare provider or pharmacist.

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

What else should I know about taking LO/OVRAL?

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

How should I store LO/OVRAL?

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

General information about the safe and effective use of LO/OVRAL.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use LO/OVRAL for a condition for which it was not prescribed. Do not give LO/OVRAL to other people.

This Patient Information summarizes the most important information about LO/OVRAL. You can ask your pharmacist or healthcare provider for information about LO/OVRAL that is written for health professionals.

Do birth control pills cause cancer?

It is not known if hormonal birth control pills cause breast cancer. Some studies, but not all, suggest that there could be a slight increase in the risk of breast cancer among current users with longer duration of use.

If you have breast cancer now, or have had it in the past, do not use hormonal birth control 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 LO/OVRAL?

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 LO/OVRAL, 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 LO/OVRAL?

Active ingredients:

White pills: norgestrel and ethinyl estradiol

Inactive ingredients:

White pills: lactose monohydrate, magnesium stearate, microcrystalline cellulose, and polacrilin potassium.

INSTRUCTIONS FOR USE

LO/OVRAL *[Low-O-Vral]*

(norgestrel and ethinyl estradiol tablets)

Important Information about taking LO/OVRAL

- 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 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 LO/OVRAL, talk to your healthcare provider.
- When you first start taking LO/OVRAL, 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 LO/OVRAL. 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, 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 LO/OVRAL 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 LO/OVRAL.
- If you have vomiting or diarrhea within **3 to 4** hours of taking a white active pill, take another white pill from your extra blister pack. If you do not have an extra blister pack, take the next white pill in your blister pack. Continue taking all your remaining pills in order. Start the first pill of your next blister pack the day after finishing your current 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 or a spermicide, until you check with your healthcare provider.
- Stop taking LO/OVRAL 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 or spermicide) during this time period.

Before you start taking LO/OVRAL:

- 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 or spermicide) available and if possible, an extra full pack of pills as needed.

When should I start taking LO/OVRAL?

If you start taking LO/OVRAL 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 or spermicide for the first **7** days that you take LO/OVRAL. You do not need back-up contraception if you use the Day 1 Start.

If you start taking LO/OVRAL and you are switching from another birth control pill:

- Start your new LO/OVRAL pack the day after the last tablet of your previous birth control method.
- Do not continue taking the pills from your previous birth control pack.

If you start taking LO/OVRAL and previously used a vaginal ring or transdermal patch:

- Start using LO/OVRAL on the day you would have reapplied the next ring or patch.

If you start taking LO/OVRAL and you are switching from a progestin-only method such as an implant or injection:

- Start taking LO/OVRAL on the day of removal of your implant or on the day when you would have had your next injection.

If you start taking LO/OVRAL and you are switching from an intrauterine device or system (IUD or IUS):

- Start taking LO/OVRAL 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 or spermicide for the first **7** days that you take LO/OVRAL.

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 LO/OVRAL?**" 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 **21** days.
- After taking the last pill on **Day 21** from the blister pack, wait 7 days (1 week) before starting a new pack.

- Start taking the first pill from a new pack, on the same day of the week as the first 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 or spermicide for the first **7** days of the first cycle that you take LO/OVRAL.

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 **21** days.
- After taking the last pill on **Day 21** from the blister pack, wait 7 days (1 week) before starting a new 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.

Instructions for using your pill pack:

Step 1.

Look at your LO/OVRAL pill pack. **See Figure A.**

The LO/OVRAL pill pack has:

- **21** "active" white pills (with hormones) to be taken for **21** days
-

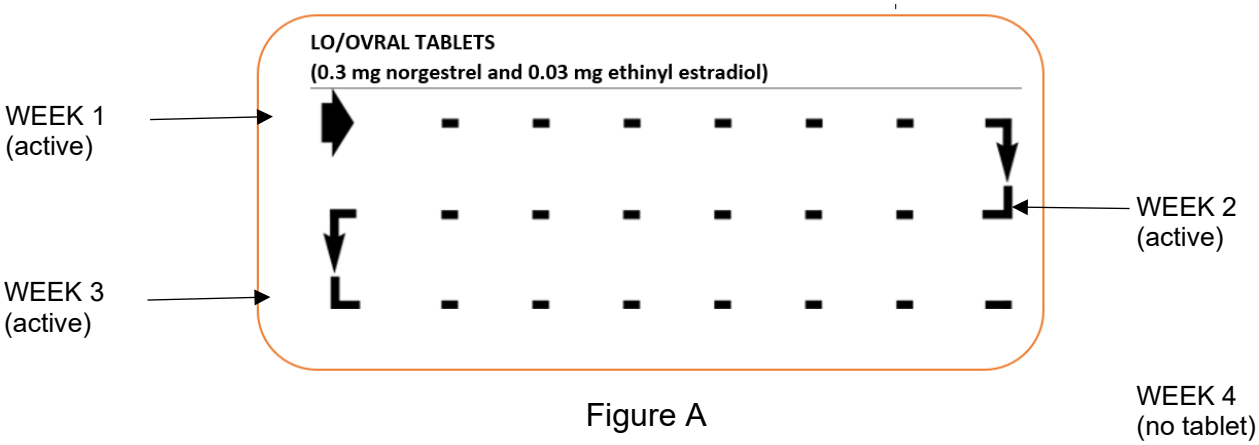


Figure A

Step 2.

Find:

Where on the pack to start taking pills (look for white pill next to the large arrow)

In what order to take the pills (follow the arrows). Follow the arrows shown in **Figure A**

Step 3.

Remove the white pill by pressing the pill through the foil in the bottom of the pill pack. **See Figure B**. Continue taking the white pills for 21 days.

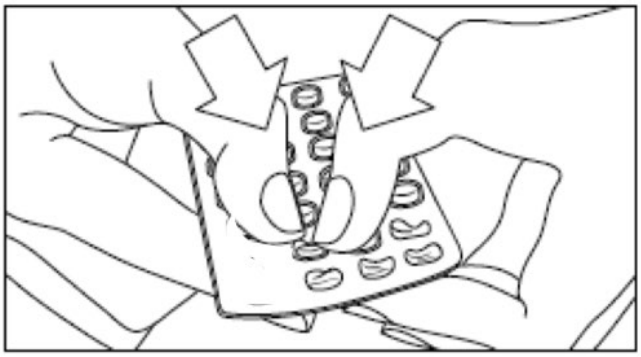


Figure B

Step 4.

After taking the last pill from the pill dispenser, wait 7 days (1 week) before starting a new pack.

For a Day 1 start:

Begin your next pill pack on the same day of the week as your first cycle pill pack.

For a Sunday Start:

Begin your next pill pack on Sunday.

What should I do if I miss any LO/OVRAL white 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 a row 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 or 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 at any time, 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.

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.
- 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 SHOULD use a non-hormonal birth control method (such as a condom or 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.

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Berkeley, CA 94707, USA

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

Revised: **10/2022**