

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use LO MINASTRIN™ FE safely and effectively. See [full prescribing information](#) for LO MINASTRIN FE.

LO MINASTRIN FE (norethindrone acetate and ethinyl estradiol tablets, ethinyl estradiol tablets and ferrous fumarate tablets), for oral use
Initial U.S. Approval: 1968

WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS

See full prescribing information for complete boxed warning.

- Women over 35 years old who smoke should not use Lo Minastrin Fe (4)
- Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptive (COC) use (4)

RECENT MAJOR CHANGES

Contraindications (4) 08/2017
Warnings (5.3) 08/2017

INDICATIONS AND USAGE

- Lo Minastrin Fe is an estrogen/progestin COC indicated for use by women to prevent pregnancy (1)
- The efficacy in women with a body mass index of more than 35 kg/m² has not been evaluated (1, 8.8)

DOSAGE AND ADMINISTRATION

- One blue tablet daily chewed and swallowed taken at the same time every day for 24 days. Follow with 8 ounces of water (2.1)
- One white tablet daily swallowed taken at the same time every day for 2 days (2.1)
- One brown tablet daily swallowed taken at the same time every day for 2 days (2.1)
- Take tablets in the order directed on the blister pack (2.1)
- Tablets may be administered without regard to meals (2.1)

DOSAGE FORMS AND STRENGTHS

Lo Minastrin Fe consists of 28 tablets in the following order (3):

- 24 blue, mint-flavored, chewable tablets (active), each containing 1 mg norethindrone acetate and 10 mcg ethinyl estradiol
- 2 white tablets (active), each containing 10 mcg ethinyl estradiol
- 2 brown tablets (non-hormonal placebo) each containing 75 mg ferrous fumarate which does not serve any therapeutic purpose

CONTRAINDICATIONS

- A high risk of arterial or venous thrombotic diseases (4)

- Breast cancer or other estrogen- or progestin-sensitive cancer (4)
- Liver tumors or liver disease (4)
- Undiagnosed abnormal uterine bleeding (4)
- Pregnancy (4)
- Hypersensitivity to any ingredients in Lo Minastrin Fe (4)
- Co-administration with Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir (4)

WARNINGS AND PRECAUTIONS

- Vascular risks: Stop Lo Minastrin Fe 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 if jaundice occurs (5.2)
- High blood pressure: If used in women with well-controlled hypertension, monitor blood pressure and stop Lo Minastrin Fe if blood pressure rises significantly (5.4)
- Carbohydrate and lipid metabolic effects: Monitor prediabetic and diabetic women taking Lo Minastrin Fe. Consider an alternative contraceptive method for women with uncontrolled dyslipidemia (5.6)
- Headache: Evaluate significant change in headaches and discontinue if indicated (5.7)
- Uterine bleeding: Evaluate irregular bleeding or amenorrhea (5.8)

ADVERSE REACTIONS

The most common adverse reactions (≥ 2%) in clinical trials were nausea/vomiting, headache, bleeding irregularities, dysmenorrhea, weight change, breast tenderness, acne, abdominal pain, anxiety and depression (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Allergan at 1-800-678-1605 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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 method 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)

See 17 for PATIENT COUNSELING INFORMATION and [FDA-approved patient labeling](#).

Revised: 08/2017

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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 Minastrin Fe is indicated for use by females of reproductive age to prevent pregnancy [see [Clinical Studies \(14\)](#)].

The efficacy of Lo Minastrin Fe in women with a body mass index (BMI) of more than 35 kg/m² has not been evaluated.

2 DOSAGE AND ADMINISTRATION

2.1 How to Take Lo Minastrin Fe

To achieve maximum contraceptive effectiveness, Lo Minastrin Fe must be taken exactly as directed. Instruct patients to take one tablet by mouth at the same time every day. The blue tablet should be chewed and swallowed. The patient should drink a full glass (8 ounces) of water immediately after chewing and swallowing the blue tablet. The white tablet and the brown tablet are swallowed. Tablets must be taken in the order directed on the blister pack. Tablets should not be skipped or taken at intervals exceeding 24 hours. For patient instructions for missed tablets [see [FDA-approved patient labeling](#)]. Lo Minastrin Fe may be administered without regard to meals [see [Clinical Pharmacology \(12.3\)](#)].

2.2 How to Start Lo Minastrin Fe

Instruct the patient to begin taking Lo Minastrin Fe on Day 1 of her menstrual cycle (that is, the first day of her menstrual bleeding) [see [FDA-approved patient labeling](#)]. One blue tablet should be taken daily for 24 consecutive days, followed by one white tablet daily for 2 consecutive days, followed by one brown tablet daily for 2 consecutive days. Instruct the patient to use a non-hormonal contraceptive as back-up during the first 7 days if she starts taking Lo Minastrin Fe other than on the first day of her menstrual cycle.

For postpartum women who do not breastfeed or after a second trimester abortion, Lo Minastrin Fe may be started no earlier than 4 weeks postpartum. Recommend use of a non-hormonal back-up method for the first 7 days. When COCs are used during the postpartum period, the increased risk of thromboembolic disease associated with the postpartum period must be considered [see [Warnings and Precautions \(5.1\)](#)]. The possibility of ovulation and conception before starting COCs should also be considered.

Lo Minastrin Fe may be initiated immediately after a first-trimester abortion or miscarriage; if the patient starts Lo Minastrin Fe immediately, additional contraceptive measures are not needed.

2.3 Switching from another Hormonal Method of Contraception

If the patient is switching from a combination hormonal method such as:

- Another pill
- Vaginal ring
- Patch
- Instruct her to take the first blue tablet on the day she would have taken her next COC pill. She should not continue taking the tablets from her previous birth control pack, and should not skip any days between packs. If she does not have a withdrawal bleed, rule out pregnancy before starting Lo Minastrin Fe.
- If she previously used a vaginal ring or transdermal patch, she should start using Lo Minastrin Fe on the day she would have resumed the previous product.

If the patient is switching from a progestin-only method such as a:

- Progestin-only pill
- Implant
- Intrauterine system
- Injection
- She may switch any day from a progestin-only pill; instruct her to take the first blue tablet on the day she would have taken her next progestin-only pill.
- If switching from an implant or injection, start the first blue tablet on the day her next injection would have been due or on the day of removal of her implant.
- If switching from an IUD, depending on the timing of removal, back-up contraception may be needed.

2.4 Advice in Case of Gastrointestinal Disturbances

If the patient vomits or has diarrhea (within 3 to 4 hours after she takes a blue or white tablet), she should follow the instructions in the “What to Do if You Miss Tablets” section [*see [FDA-approved patient labeling](#)*].

3 DOSAGE FORMS AND STRENGTHS

Lo Minastrin Fe is available in blister packs.

Each blister pack contains 28 tablets in the following order:

- 24 blue, round, chewable, mint-flavored (active) tablets imprinted with “WC” on one side and “537” on the other and each containing 1 mg norethindrone acetate and 10 mcg ethinyl estradiol.
- 2 white, hexagonal (active) tablets imprinted with “WC” on one side and “422” on the other and each containing 10 mcg ethinyl estradiol.
- 2 brown, round (non-hormonal placebo) tablets imprinted with “WC” on one side and “624” on the other and each containing 75 mg ferrous fumarate. The ferrous fumarate tablets do not serve any therapeutic purpose.

4 CONTRAINDICATIONS

Do not prescribe Lo Minastrin Fe 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 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 inherited or acquired hypercoagulopathies [*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 [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 \(5.11\)](#)*]
- Hypersensitivity to any ingredients in Lo Minastrin Fe
- 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 \(5.3\)](#)*]

5 WARNINGS AND PRECAUTIONS

5.1 Thromboembolic Disorders and Other Vascular Problems

Stop Lo Minastrin Fe if an arterial or deep venous thrombotic event (VTE) occurs. Stop Lo Minastrin Fe if there is unexplained loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions. Evaluate for retinal vein thrombosis immediately.

If feasible, stop Lo Minastrin Fe at least 4 weeks before and through 2 weeks after major surgery or other surgeries known to have an elevated risk of VTE.

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