XELRIA FE- norethindrone and ethinyl estradiol and ferrous fumarate
Xiromed LLC

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use XELRIA FE safely and effectively. See full prescribing information for XELRIA FE.
XELRIA™ FE (norethindrone and ethinyl estradiol chewable tablets and ferrous fumarate chewable tablets), for oral use
Initial U.S. Approval: 1975

WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS
See Full Prescribing Information for complete boxed warning.
- **Xelria Fe 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)**

INDICATIONS AND USAGE
Xelria Fe is a progestin/estrogen COC indicated for use by females of reproductive potential to prevent pregnancy. (1)

DOSAGE AND ADMINISTRATION
- Take one tablet by mouth at the same time every day. Tablets may be chewed or swallowed. (2.1)
- Take tablets in the order directed on the blister pack. (2.1)

DOSAGE FORMS AND STRENGTHS
Xelria Fe consists of 28 tablets in the following order (3):
- 21 yellow tablets (active), each containing 0.4 mg norethindrone and 0.035 mg ethinyl estradiol
- 7 brown tablets (non-hormonal placebo), each containing 75 mg ferrous fumarate. The ferrous fumarate tablets do not serve any therapeutic purpose.

CONTRAINDICATIONS
- A high risk of arterial or venous thrombotic diseases (4)
- Liver tumors or liver disease (4)
- Undiagnosed abnormal uterine bleeding (4)
- Pregnancy (4)
- Current diagnosis of, or history of, breast cancer, which may be hormone-sensitive (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 norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) 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 norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) if jaundice occurs (5.2)
- High blood pressure: If used in women with well-controlled hypertension, monitor blood pressure and stop norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) if blood pressure rises significantly. (5.4)
- Carbohydrate and lipid metabolic effects: Monitor prediabetic and diabetic women taking norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable). Consider an alternative contraceptive method for women with uncontrolled dyslipidemia (5.6)
- Headache: Evaluate significant change in headaches and discontinue norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) if indicated (5.7)
- Bleeding Irregularities and Amenorrhea: Evaluate irregular bleeding or amenorrhea (5.8)

ADVERSE REACTIONS
The most common adverse reactions were: irregular uterine bleeding, nausea, breast tenderness, and headache. (6)
To report SUSPECTED ADVERSE REACTIONS, contact Xiromed, LLC at 1-844-XIROMED (1-844-947-6633) 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: Advise use of another contraceptive method. Norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) can decrease milk production. (8.3)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.
Revised: 10/2024

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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 are contraindicated in women who are over 35 years of age and smoke *[see Contraindications (4)]*

1 INDICATIONS AND USAGE

Xelria Fe is indicated for use by females of reproductive potential to prevent pregnancy.

2 DOSAGE AND ADMINISTRATION

2.1 How to Start Xelria Fe

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

Xelria Fe (yellow active tablets and brown placebo tablets) may be swallowed whole or chewed and swallowed. If the tablet is chewed, the patient should drink a full glass (8 ounces) of liquid immediately after swallowing.

Table 1: Instructions for Administration of Xelria Fe

Starting CHCs in women not currently using hormonal contraception (Day 1 Start or Sunday Start) **Important:**	**Day 1 Start:** • Take first yellow active tablet on the first day of menses. • Take subsequent yellow active tablets once daily at the same time each day for a total of 21 days.

Consider the possibility of ovulation and conception prior to initiation of this product. **Tablet Color:** • Norethindrone and ethinyl estradiol active tablets (chewable) are yellow (Day 1 to Day 21). • Ferrous fumarate (chewable) placebo tablets are brown (Day 22 to Day 28).	• Take one **brown** placebo tablet daily for 7 days and at the same time of day that active tablets were taken. • Begin each subsequent pack on the same day of the week as the first cycle pack (i.e., on the day after taking the last inactive tablet).
	Sunday Start: • Take first active tablet 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 pack of norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable).** • Take subsequent **yellow** active tablets once daily at the same time each day for a total of 21 days. • Take one **brown** placebo tablet daily for the following 7 days and at the same time of day that active tablets were taken. • Begin each subsequent pack on the same day of the week as the first cycle pack (i.e., on the Sunday after taking the last inactive tablet) and additional non-hormonal contraceptive is not needed.
Switching to norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) from another hormonal contraceptive	Start on the same day that a new pack of the previous hormonal contraceptive would have started.
Switching from another contraceptive method to norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable)	**Start norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable):**
• **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 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 Xelria Fe after Abortion or Miscarriage

First-trimester
- After a first-trimester abortion or miscarriage, Xelria Fe may be started immediately. An additional method of contraception is not needed if Xelria Fe is started within 5 days after termination of the pregnancy.
- If Xelria Fe 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 pack of Xelria Fe.

Second-trimester
- Do not start until 4 weeks after a second-trimester abortion or miscarriage, due to the increased risk of thromboembolic disease. Start Xelria Fe, 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 pack of Xelria Fe. *[See Contraindications (4), Warnings and Precautions (5.1), and FDA-Approved Patient Labeling.]*

Starting Xelria Fe after Childbirth
- Do not start until 4 weeks after delivery, due to the increased risk of thromboembolic disease. Start contraceptive therapy with Xelria Fe 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 Xelria Fe. *[See Contraindications (4), Warnings and Precautions (5.1), Use in Specific Populations (8.1 and 8.3), and FDA-Approved Patient Labeling].*

2.3 Missed Tablets

Table 2: Instructions for Missed Xelria Fe

• If one yellow 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 yellow 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. **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 yellow active tablets are missed in Week 3 or three or more yellow 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. **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.**

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 an active tablet, handle this as a missed tablet *[see FDA-Approved Patient Labeling]*.

3 DOSAGE FORMS AND STRENGTHS

Xelria Fe is available in cartons of 3 blister packs.

Each blister pack contains 28 tablets in the following order:
- 21 yellow, round, uncoated flat (active) tablets debossed with "226" on one side of the tablet and plain on the other side and each containing 0.4 mg norethindrone and 0.035 mg ethinyl estradiol.
- 7 brown, round (non-hormonal placebo) tablets debossed with "291" on one side of the tablet and plain on the other side and each containing 75 mg ferrous fumarate. The ferrous fumarate tablets do not serve any therapeutic purpose.

4 CONTRAINDICATIONS

Xelria Fe is contraindicated in females who are known to have or develop the following conditions:
- A high risk of arterial or venous thrombotic diseases. Examples include women who are known to:

o Smoke, if over age 35 *[see Boxed Warning* and *Warnings and Precautions (5.1)]*

o Have deep vein thrombosis or pulmonary embolism, now or in the past *[see Warnings and Precautions (5.1)]*

o Have inherited or acquired hypercoagulopathies *[see Warnings and Precautions (5.1)]*

o Have cerebrovascular disease *[see Warnings and Precautions (5.1)]*

o Have coronary artery disease *[see Warnings and Precautions (5.1)]*

o 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)]*

o Have uncontrolled hypertension *[see Warnings and Precautions (5.4)]*

o Have diabetes mellitus with vascular disease *[see Warnings and Precautions (5.6)]*

o 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)]*
- Current diagnosis of, or history of, breast cancer, which may be hormone-sensitive *[see Warnings and Precautions (5.11)]*
- Hypersensitivity to any of the components.
- 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 Thrombotic Disorders and Other Vascular Problems
- Stop norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) if an arterial thrombotic event or venous thromboembolic (VTE) event occurs.
- Stop norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) if there is unexplained loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions. Evaluate for retinal vein thrombosis immediately.
- If feasible, stop norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) 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 the following prolonged immobilization.
- Start norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate

tablets (chewable) 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 per 10,000 woman-years. The risk of VTE is highest during the first year of use of COCs and when restarting hormonal contraception after a break of 4 weeks or longer. The risk of thromboembolic disease due to COCs gradually disappears after use is discontinued.
- Use of COCs also increases the risk of arterial thromboses such as 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). The 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.

5.2 Liver Disease

Impaired Liver Function

Do not use norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) 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 norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) if jaundice develops.

Liver Tumors

Norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) are 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.

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 women using ethinyl estradiol-containing medications, such as COCs. Discontinue norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) prior to starting therapy with the combination drug regimen ombitasvir/paritaprevir/ritonavir, with or without dasabuvir *[see Contraindications (4)]*. Norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) can be restarted approximately 2 weeks following completion of treatment with the Hepatitis C combination drug regimen.

5.4 High Blood Pressure

Norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) are 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 norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) 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 Effects

Carefully monitor prediabetic and diabetic women who take norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable). 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.

5.7 Headache

If a woman taking norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) develops new headaches that are recurrent, persistent, or severe, evaluate the cause and discontinue norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) if indicated.

Consider discontinuation of norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) 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 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.

Amenorrhea and Oligomenorrhea

Women who use norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) may experience amenorrhea. 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 COC Use Before or During Early Pregnancy

Extensive epidemiologic 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 norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) 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 norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) if depression recurs to a serious degree.

5.11 Malignant Neoplasms

Breast Cancer

Norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) are contraindicated in females 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 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 norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable).

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:

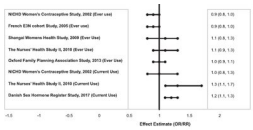
- Irregular uterine bleeding
- Nausea
- Breast tenderness
- Headache

6.2 Post Marketing 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. Risk of Breast Cancer with Combined Oral Contraceptive Use



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.

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 hormonal contraceptives include phenytoin, barbiturates, carbamazepine, bosentan, felbamate, griseofulvin, oxcarbazepine, rifampicin, topiramate, rifabutin, rufinamide, aprepitant, and products containing St. John's wort. Interactions between hormonal contraceptives and other drugs may lead to breakthrough bleeding and/or contraceptive failure. Counsel women to ue an alternative method of contraception or a back-up method when enzyme inducers are used with COCs, and to continue back-up 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 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. CYP3A4 inhibitors, such as itraconazole, 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 (decrease [e.g., nevirapine] or increase [e.g., etravirine]).

7.2 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, temazepam and lamotrigine. 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 (5.12)]*.

7.3 Concomitant Use with HCV Combination Therapy - Liver Enzyme Elevation

Do not co-administer norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) with HCV drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, due to potential for ALT elevations *[see Warnings and Precautions (5.3)]*.

7.4 Interference 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

There is little or no increased risk of birth defects in women who inadvertently use COCs during early pregnancy. Epidemiologic studies and meta-analyses have not found an increased risk of genital or non-genital birth defects (including cardiac anomalies and limb reduction defects) following exposure to low dose COCs prior to conception or during early pregnancy.

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

8.3 Nursing Mothers

Advise the nursing mother to use other forms of contraception, when possible, until she has weaned her child. COCs can reduce milk production in breastfeeding mothers. This is less likely to occur once breastfeeding is well-established; however, it can occur at any time in some women. Small amounts of oral contraceptive steroids and/or metabolites are present in breast milk.

8.4 Pediatric Use

Safety and efficacy of norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) have been established in women of reproductive age. Efficacy is expected to be the same in post-pubertal adolescents under the age of 18 years as for users 18 years and older. Use of this product before menarche is not indicated.

8.5 Geriatric Use

Norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) have not been studied in postmenopausal women and is not indicated in this population.

8.6 Hepatic Impairment

The pharmacokinetics of norethindrone and ethinyl estradiol tablets (chewable) and

ferrous fumarate tablets (chewable) has not been studied in women 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

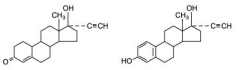
The pharmacokinetics of norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) has not been studied in women with renal impairment.

10 OVERDOSAGE

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

11 DESCRIPTION

Xelria Fe is a combinational contraceptive containing the progestational compound norethindrone and the estrogenic compound ethinyl estradiol. The packaging includes 21 yellow tablets composed of norethindrone and ethinyl estradiol followed by 7 brown ferrous fumarate (placebo) tablets. The chemical name for norethindrone is 17-hydroxy-19-nor-17α-pregn-4-en-20-yn-3-one and for ethinyl estradiol the chemical name is 19-nor-17α-pregna-1,3,5(10)-trien-20-yne-3,17-diol. The structural formulas are:



NORETHINDRONE

ETHINYL ESTRADIOL

The active yellow norethindrone and ethinyl estradiol tablets (chewable) contain 0.4 mg norethindrone and 0.035 mg ethinyl estradiol, and the following inactive ingredients: colloidal silicon dioxide, dibasic calcium phosphate, D & C Yellow No.10 Aluminium Lake, lactose anhydrous, lactose monohydrate, magnesium stearate, maltodextrin, povidone K-30, sodium starch glycolate, spearmint flavor and sucralose.

The brown tablets contain ferrous fumarate, colloidal silicon dioxide, crosscarmellose sodium, lactose monohydrate, magnesium stereate, microcrystalline cellulose and povidone K-90.The ferrous fumarate tablets do not serve any therapeutic purpose. Ferrous fumarate tablets are not USP for dissolution and assay.

USP Dissolution Test is pending.

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.

12.2 Pharmacodynamics

No specific pharmacodynamic studies were conducted with norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable).

12.3 Pharmacokinetics

Absorption

Ethinyl estradiol and norethindrone are rapidly absorbed with maximum plasma concentrations occurring within 2 hours after norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) administration (see Table 1).

Norethindrone appears to be completely absorbed following oral administration; however, it is subject to first-pass metabolism resulting in an absolute bioavailability of approximately 65 percent. Large intersubject variability is reflected in a 3- to 5-fold variation in norethindrone bioavailability. Ethinyl estradiol bioavailability is approximately 43 percent due to small-intestinal and hepatic first-pass metabolism.

Table 3. Mean ±SD Pharmacokinetic Parameters Following Single Dose Administration of Norethindrone and Ethinyl Estradiol Tablets (chewable) and Ferrous Fumarate Tablets (chewable) in Healthy Female Subjects Under Fasting Conditions.

Norethindrone/Ethinyl Estradiol	t_{max} (h)	C_{max} (pg/mL)	$AUC_{0-\infty}$ (pg•h/mL)	$t_{1/2}$ (h)
Norethindrone 0.4 mg	1.24 ± 0.40[a]	4210.6 ± 1628.8[a]	18034.9 ± 7852.9[b]	8.6 ± 3.7[b]
Ethinyl Estradiol 0.035 mg	1.44 ± 0.33[b]	131.4 ± 34.2[b]	1065.8 ± 276.2[b]	17.1 ± 4.4[b]

[a]n = 26 [b]n = 25 C_{max} = maximum plasma concentration; t_{max} = time to reach C_{max}; AUC = area under the curve; $t_{1/2}$ = elimination half- life.

Food Effect

Single-dose administration of norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) with food decreased the maximum norethindrone and ethinyl estradiol concentration by 53 percent and 47 percent, respectively; the extent of norethindrone and ethinyl estradiol absorption (AUC values) was not affected by food administration.

Distribution

Norethindrone is 36 percent bound to sex hormone-binding globulin (SHBG) and 61 percent bound to albumin. Ethinyl estradiol is not bound to SHBG but is highly (98.5 percent) bound to albumin. Volume of distribution of norethindrone and ethinyl estradiol ranges from 2 to 4 L/kg.

Metabolism

Norethindrone undergoes extensive biotransformation, primarily via reduction, followed by sulfate and glucuronide conjugation; less than 5 percent of a norethindrone dose is excreted unchanged; greater than 50 percent and 20 to 40 percent of a dose is excreted in urine and feces, respectively. The majority of metabolites in the circulation are sulfates, with glucuronides accounting for most of the urinary metabolites.

Ethinyl estradiol is also extensively metabolized, both by oxidation and by conjugation with sulfate and glucuronide. Sulfates are the major circulating conjugates of ethinyl estradiol, and glucuronides predominate in urine. The primary oxidative metabolite is 2-hydroxy-ethinyl estradiol, which is formed by the CYP3A4 isoform of cytochrome P450.

Excretion

Plasma clearance values for norethindrone and ethinyl estradiol are similar (approximately 0.4 L/hr/kg). Ethinyl estradiol and norethindrone are excreted in both urine and feces, primarily as metabolites. Ethinyl estradiol is excreted in urine and feces as glucuronides and sulfates, and about 28 to 43 percent undergoes enterohepatic circulation. The mean terminal elimination half-lives of norethindrone and ethinyl estradiol following single dose administration of norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) are approximately 9 hours and 17 hours, respectively.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

[See Warnings and Precautions (5.11) and Use in Specific Populations (8.1).]

14 CLINICAL STUDIES

The data presented in Section 14 are from a clinical trial conducted with norethindrone 0.4 mg/ethinyl estradiol 0.035 mg tablets. Norethindrone and ethinyl estradiol tablets (chewable) and ferrous fumarate tablets (chewable) are bioequivalent to these norethindrone/ethinyl estradiol tablets.

In a multicenter open-label clinical trial, 1,970 women, 98% of whom were 16 to 39 years of age, were studied for up to 31 cycles (28 days per cycle) to assess the efficacy of norethindrone /ethinyl estradiol tablets, completing the equivalent of 20,230 cycles of exposure. The racial demographic of all enrolled women was: Caucasian (56%), African-American (14%), and Other (30%) (Hispanic, Native American, etc.). Of treated women, 10% were lost to follow-up, 11% discontinued related to cycle control and 7% discontinued due to other adverse events

The pregnancy rate (Pearl Index [PI]) in all 1,970 women was 1.48 pregnancies per 100 women-years of use (95% confidence interval 0.94 to 2.22), based on 23 pregnancies that occurred after the onset of treatment of norethindrone /ethinyl estradiol tablets.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

Xelria Fe is available in cartons of 3 blister packs:

NDC 70700-308-85

Each blister pack contains 28 tablets in the following order:

- 21 yellow, round, uncoated flat (active) tablets debossed with “226” on one side of the tablet and plain on the other side and each containing 0.4 mg norethindrone and

0.035 mg ethinyl estradiol.
- 7 brown, round (non-hormonal placebo) tablets debossed with "291" on one side of the tablet and plain on the other side and each containing 75 mg ferrous fumarate.

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)]*.
- Xelria Fe does not protect against HIV infection (AIDS) and other sexually transmitted diseases.
- Xelria Fe is not to be used during pregnancy; if pregnancy occurs during use of Xelria Fe, 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 pills are missed *[see Dosage and Administration (2.3)]*.
- Use a back-up or alternative method of contraception when enzyme inducers are used with Xelria Fe *[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)]*.
- A woman who starts COCs postpartum and who has not yet had a period should use an additional method of contraception until she has taken a yellow 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 (5.8)]*.

PATIENT INFORMATION

Xelria Fe (Norethindrone and Ethinyl Estradiol Tablets, USP (Chewable) and Ferrous Fumarate Tablets (Chewable))

What is the most important information I should know about Xelria Fe?

Do not use Xelria Fe if you smoke cigarettes and are over 35 years old. Smoking increases your risk of serious cardiovascular side effects (heart and blood vessel problems) from 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 Xelria Fe?

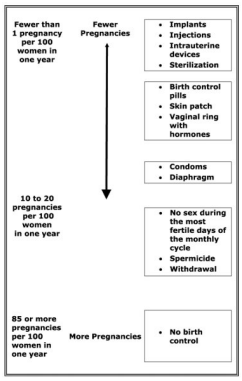
Xelria Fe is a birth control pill (oral contraceptive) used by women to prevent pregnancy.

How does Xelria Fe 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 one clinical study of a 28-day regimen of norethindrone 0.4 mg/ethinyl estradiol 0.035 mg tablets, about 1 to 2 out of 100 women may get pregnant during the first year they use Xelria Fe.

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 Xelria Fe?

Do not take Xelria Fe 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
- have any unexplained vaginal bleeding
- are pregnant
- had breast cancer or any cancer that is sensitive to female hormones
- 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

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

What should I tell my healthcare provider before taking Xelria Fe?

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. Xelria Fe may decrease the amount of breast milk you make. A small amount of the hormones in Xelria Fe 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.

Xelria Fe may affect the way other medicines work, and other medicines may affect how well Xelria Fe work.

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

How do I take Xelria Fe?

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

What are the possible serious side effects of Xelria Fe?
- **Like pregnancy, Xelria Fe 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

- 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**
- **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 Xelria Fe. Use sunscreen if you have to be in the sunlight.

What are the most common side effects of Xelria Fe?

The most common side effects of Xelria Fe include:
- headache (including migraine)
- nausea and vomiting
- breast problems

o tenderness, pain and discomfort

o enlargement and swelling

o discharge

o nipple pain
- belly pain
- pain with your periods (menstrual cycle)
- mood changes, including depression
- acne
- vaginal infections
- bloating
- weight gain

These are not all the possible side effects of Xelria Fe. 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 Xelria Fe?
- If you are scheduled for any lab tests, tell your healthcare provider you are taking Xelria Fe. Certain blood tests may be affected by Xelria Fe.
- Xelria Fe does not protect against HIV infection (AIDS) and other sexually transmitted infections.

How should I store Xelria Fe?
- Store Xelria Fe at room temperature between 20° to 25°C (68° to 77°F).
- Keep Xelria Fe and all medicines out of the reach of children.
- Store away from light.

General information about the safe and effective use of Xelria Fe.

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

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

For more information, call Xiromed, LLC at 1-844-XIROMED (1-844-947-6633).

Does hormonal birth control 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 Xelria Fe?

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 Xelria Fe, 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 Xelria Fe?

Active ingredients:

Yellow pills: norethindrone and ethinyl estradiol

Brown pills: ferrous fumarate

Inactive ingredients:

Yellow pills: colloidal silicon dioxide, dibasic calcium phosphate, D & C Yellow No.10 Aluminium Lake, lactose anhydrous, lactose monohydrate, magnesium stearate, maltodextrin, povidone K-30, sodium starch glycolate, spearmint flavor and sucralose

Brown pills: colloidal silicon dioxide, crosscarmellose sodium, lactose monohydrate, magnesium stereate, microcrystalline cellulose and povidone K-90

INSTRUCTIONS FOR USE
Xelria Fe (Norethindrone and Ethinyl Estradiol Tablets, USP (Chewable) and Ferrous Fumarate Tablets (Chewable))

Important Information about taking Xelria Fe.
- Take **1** pill every day at the same time. Take the pills in the order directed on your blister pack.
- Both the yellow pills and the brown pills may be swallowed whole or chewed and swallowed. **If the pill is chewed, drink a full glass (8 ounces) of liquid immediately after swallowing.**
- 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 Xelria Fe, talk to your healthcare provider. When you first start taking Xelria Fe, 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 Xelria Fe. 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 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 Xelria Fe 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 Xelria Fe.
- 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 blister pack. If you do not have an extra blister pack, take the next 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 and a spermicide, until you check with your healthcare provider.
- Stop taking Xelria Fe 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 Xelria Fe:
- 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 pack of pills as needed.

When should I start taking Xelria Fe?

If you start taking Xelria Fe 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 Xelria Fe. You do not need back-up contraception if you use the Day 1 Start.

If you start taking Xelria Fe and you are switching from another birth control pill:
- Start your new Xelria Fe 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 Xelria Fe and previously used a vaginal ring or transdermal patch:
- Start using Xelria Fe on the day you would have reapplied the next ring or patch.

If you start taking Xelria Fe and you are switching from a progestin-only method such as an implant or injection:
- Start taking Xelria Fe on the day of removal of your implant or on the day when you would have had your next injection.

If you start taking Xelria Fe and you are switching from an intrauterine device or system (IUD or IUS):
- Start taking Xelria Fe 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 Xelria Fe.

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 Xelria Fe?**" 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 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 and spermicide for the first **7** days of the first cycle that you take Xelria Fe.

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.

Instructions for using your pill pack:

Step 1.

Look at your Xelria Fe pill pack. **See Figure A.**

The Xelria Fe pill pack has:
- **21** yellow (active) pills with hormone for **Week 1 through Week 3.**
- **7** brown (inactive) pills without hormones for **Week 4.**

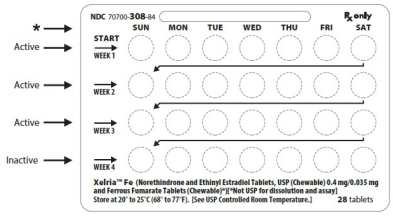


Figure A

Step 2.

Find:
- where on your pack to start taking pills
- in what order to take your pills (follow the arrows)
- the week numbers

Step 3.

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

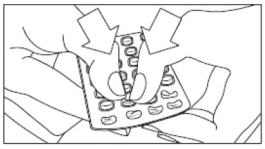


Figure B

Step 4.

On the first day of **Week 4** start taking the brown pills. Take the brown pill for **7 days**. Your period should start during this time.

Step 5.

When you have taken all of the brown pills in your pill pack, get a new pill pack and start taking the yellow pills.
- **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 Xelria Fe 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.

- **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 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 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.

Manufactured for:
Xiromed, LLC
Florham Park, NJ 07932

Product of India

Code No.: GUJ-DRUGS/G/28/1297

PI-308-00

Revised: 10/2024

PRINCIPAL DISPLAY PANEL - 0.4 mg /0.035 mg

NDC 70700-308-85

Rx only

Xelria Fe (Norethindrone and Ethinyl Estradiol Tablets USP (Chewable) andFerrous Fumarate Tablets (Chewable))*

0.4 mg /0.035 mg

3 pouches, each pouch contains one blister pack of 28 tablets

XELRIA FE
norethindrone and ethinyl estradiol and ferrous fumarate kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70700-308

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70700-308-85	3 in 1 CARTON	01/29/2025	
1	NDC:70700-308-84	1 in 1 POUCH		
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1		21
Part 2		7

Part 1 of 2

NORETHINDRONE AND ETHINYL ESTRADIOL
norethindrone and ethinyl estradiol tablet, chewable

Product Information	
Item Code (Source)	NDC:70700-861
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
NORETHINDRONE (UNII: T18F433X4S) (NORETHINDRONE - UNII:T18F433X4S)	NORETHINDRONE	0.4 mg
ETHINYL ESTRADIOL (UNII: 423D2T571U) (ETHINYL ESTRADIOL - UNII:423D2T571U)	ETHINYL ESTRADIOL	0.035 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
D&C YELLOW NO. 10 (UNII: 35SW6USQ3G)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POVIDONE K30 (UNII: U725QWY32X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SPEARMINT (UNII: J7I2T6IV1N)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color	YELLOW	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	226
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202086	01/29/2025	

Part 2 of 2

FERROUS FUMARATE
ferrous fumarate tablet, chewable

Product Information	
Item Code (Source)	NDC:70700-846
Route of Administration	ORAL

Inactive Ingredients	
Ingredient Name	**Strength**
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERROUS FUMARATE (UNII: RSL48RRY0Q)	75 mg
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics			
Color	BROWN	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	291
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202086	01/29/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202086	01/29/2025	

Labeler - Xiromed LLC (080228637)

Revised: 10/2024 Xiromed LLC