GENERESS FE- norethindrone and ethinyl estradiol and ferrous fumarate
Allergan, Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use GENERESS® Fe safely and effectively. See full prescribing information for GENERESS Fe.

GENERESS Fe (norethindrone and ethinyl estradiol chewable tablets and ferrous fumarate chewable tablets)
Initial U.S. Approval: 1974

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 GENERESS 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 (5.4)	08/2017

INDICATIONS AND USAGE

- GENERESS Fe is an estrogen/progestin COC indicated for use by women to prevent pregnancy. (1)
- The efficacy in women with a body mass index (BMI) of > 35 kg/m^2 has not been evaluated. (1, 8.8)

DOSAGE AND ADMINISTRATION

- Chew one tablet without water at the same time every day. (2.1)
- Take tablets in the order directed on the blister pack. (2.1)

DOSAGE FORMS AND STRENGTHS

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

- 24 light green, round tablets (active) each containing 0.8 mg norethindrone and 0.025 mg ethinyl estradiol.
- 4 brown, round 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)
- Undiagnosed abnormal uterine bleeding. (4)
- Breast cancer or other estrogen- or progestin-sensitive cancer. (4)
- Liver tumors or liver disease. (4)
- Pregnancy. (4)
- Co-administration with Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir (4)

WARNINGS AND PRECAUTIONS

- Vascular risks: Stop GENERESS Fe if a thrombotic event occurs. Stop at least 4 weeks before and through 2 weeks after major surgery. Start no earlier than 4 weeks after delivery in women who are not breastfeeding. (5.1)
- Liver disease: Discontinue if jaundice occurs. (5.3)
- High blood pressure: Do not prescribe for women with uncontrolled hypertension or hypertension with vascular disease. (5.5)
- Carbohydrate and lipid metabolic effects: Monitor prediabetic and diabetic women taking GENERESS Fe. Consider an alternate contraceptive method for women with uncontrolled dyslipidemia. (5.7)
- Headache: Evaluate significant change in headaches and discontinue if indicated. (5.8)
- Uterine bleeding: Evaluate irregular bleeding or amenorrhea. (5.9)

ADVERSE REACTIONS

The most common adverse reactions (≥ 2%) are nausea/vomiting (8.8%), headaches/migraine (7.5%), depression/mood

complaints (4.1%), dysmenorrhea (3.9%), acne (3.2%), anxiety symptoms (2.4%), breast pain/tenderness (2.4%), and increased weight (2.3%). (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: 5/2018

FULL PRESCRIBING INFORMATION: CONTENTS*

* 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

GENERESS Fe is indicated for use by women to prevent pregnancy.

The efficacy of GENERESS Fe 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 Take GENERESS Fe

To achieve maximum contraceptive effectiveness, GENERESS Fe must be taken exactly as directed. Chew and swallow one tablet without water at the same time every day. 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 pills, see FDA-Approved Patient Labeling. GENERESS Fe may be administered without regard to meals *[see Clinical Pharmacology (12.3)]*.

2.2 How to Start GENERESS Fe

Instruct the patient to begin taking GENERESS Fe on Day 1 of her menstrual cycle (that is, the first day of her menstrual bleeding). One light green tablet should be taken daily for 24 consecutive days

followed by one brown tablet daily for 4 consecutive days *[see FDA-Approved Patient Labeling]*. Instruct the patient to use a non-hormonal contraceptive as back-up during the first 7 days if she starts taking GENERESS Fe other than on the first day of her menstrual cycle.

For postpartum women who do not breastfeed or after a second trimester abortion, GENERESS 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 combined oral contraceptives (COCs) are used during the postpartum period, the increased risk of thromboembolic disease associated with the postpartum period must be considered. The possibility of ovulation and conception before starting COCs should also be considered.

If the patient is switching from a combination hormonal method such as:
- Another pill
- Vaginal ring
- Patch

- Instruct her to take the first light green pill on the day she would have started a new cycle of her previous birth control pack (Day 1).
- If she previously used a vaginal ring or transdermal patch, she should start using GENERESS Fe on the day she would have restarted the ring or patch.
- Instruct the patient to use a non-hormonal back-up method such as a condom and spermicide for the first 7 days.

If the patient is switching from a progestin-only method such as:
- Progestin-only pill
- Implant
- Intrauterine system
- Injection

- Instruct her to take the first light green pill on the day she would have taken her next progestin-only pill or on the day of removal of her implant or intrauterine system or on the day when she would have had her next injection.
- Instruct the patient to use a non-hormonal back-up method such as a condom and spermicide for the first 7 days.

2.3 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 3-4 hours after taking a light green tablet, this can be regarded as a missed tablet *[see FDA-Approved Patient Labeling]*.

3 DOSAGE FORMS AND STRENGTHS

GENERESS Fe is available in blister packs.

Each blister pack (28 tablets) contains in the following order:
- 24 light green, round tablets (active) imprinted with “WC” on one side and “483” on the other and each containing 0.8 mg norethindrone and 0.025 mg ethinyl estradiol.
- 4 brown, round tablets (non-hormonal placebo) imprinted with “WC” on one side and “624” on the other and each containing 75 mg ferrous fumarate. The ferrous fumarate chewable tablets do not serve any therapeutic purpose.

4 CONTRAINDICATIONS

Do not prescribe GENERESS Fe to women who are known to have the following:
- 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 (5.5)]*
- Have diabetes with vascular disease *[see Warnings and Precautions (5.7)]*
- Have headaches with focal neurological symptoms or have migraine headaches with or without aura if over age 35 *[see Warnings and Precautions (5.8)]*

- Breast cancer or other estrogen- or progestin-sensitive cancer, now or in the past *[see Warnings and Precautions (5.2)*]
- Liver tumors, benign or malignant, or liver disease *[see Warnings and Precautions (5.3), Use in Specific Populations (8.7),* and *Clinical Pharmacology (12.3)]*
- Undiagnosed abnormal uterine bleeding *[see Warnings and Precautions (5.9)]*
- Pregnancy, because there is no reason to use COCs during pregnancy *[see Warnings and Precautions (5.10)* and *Use in Specific Populations (8.1)]*
- 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 (5.4)]*

5 WARNINGS AND PRECAUTIONS

5.1 Thrombotic and Other Vascular Events

Stop GENERESS Fe if an arterial or deep venous thrombotic (VTE) event occurs. Although the use of COCs increases the risk of venous thromboembolism, pregnancy increases the risk of venous thromboembolism as much or more than the use of COCs. The risk of venous thromboembolism in women using COCs is 3 to 9 per 10,000 woman-years. The excess risk is highest during the first year of use of a COC. 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. The risk of thromboembolic disease due to oral contraceptives gradually disappears after COC use is discontinued.

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

Start GENERESS Fe no earlier than 4 weeks after delivery, in women who are not breastfeeding. The risk of postpartum thromboembolism decreases after the third postpartum week, whereas the risk of ovulation increases after the third postpartum week.

COCs have been shown to increase both the relative and attributable risks of cerebrovascular events (thrombotic and hemorrhagic strokes), although, in general, the risk is greatest among older (> 35 years of age), hypertensive women who also smoke. COCs also increase the risk for stroke in women with other underlying risk factors.

Oral contraceptives must be used with caution in women with cardiovascular disease risk factors.

Stop GENERESS Fe if there is unexplained loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions. Evaluate for retinal vein thrombosis immediately.

5.2 Carcinoma of the Breasts and Reproductive Organs

Women who currently have or have had breast cancer should not use GENERESS Fe because breast cancer is a hormonally-sensitive tumor.

There is substantial evidence that COCs do not increase the incidence of breast cancer. Although some past studies have suggested that COCs might increase the incidence of breast cancer, more recent

studies have not confirmed such findings.

Some studies suggest that 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.

5.3 Liver Disease

Discontinue GENERESS Fe if jaundice develops. Steroid hormones may be poorly metabolized in patients with impaired liver function. 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.

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 attributable risk of liver cancers in COC users is less than one case per million users.

Oral contraceptive-related cholestasis may occur in women with a history of pregnancy-related cholestasis. Women with a history of COC-related cholestasis may have the condition recur with subsequent COC use.

5.4 Risk of Liver Enzyme Elevations with Concomitant Hepatitis C Treatment

During clinical trials with 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 GENERESS Fe prior to starting therapy with the combination drug regimen ombitasvir/paritaprevir/ritonavir, with or without dasabuvir *[see Contraindications (4)]*. GENERESS Fe can be restarted approximately 2 weeks following completion of treatment with the Hepatitis C combination drug regimen.

5.5 High Blood Pressure

For women with well-controlled hypertension, monitor blood pressure and stop GENERESS Fe if blood pressure rises significantly. Women with uncontrolled hypertension or hypertension with vascular disease should not use COCs.

An increase in blood pressure has been reported in women taking COCs, and this increase is more likely in older women and with extended duration of use. The incidence of hypertension increases with increasing concentration of progestin.

5.6 Gallbladder Disease

Studies suggest the relative risk of developing gallbladder disease may be increased among COC users.

5.7 Carbohydrate and Lipid Metabolic Effects

Carefully monitor prediabetic and diabetic women who are taking GENERESS Fe. COCs may decrease glucose tolerance in a dose-related fashion.

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.

5.8 Headache

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

An increase in frequency or severity of migraine during COC use (which may be prodromal of a cerebrovascular event) may be a reason for immediate discontinuation of the COC.

5.9 Bleeding Irregularities

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 COC.

Patient diaries from the clinical trial of GENERESS Fe showed that on the first cycle of use, 37% of subjects taking GENERESS Fe had unscheduled bleeding and/or spotting. From Cycle 2-13, the percent of women with unscheduled bleeding/spotting ranged from 21-31% per cycle. For those women with unscheduled bleeding/spotting, the mean number of days of unscheduled bleeding/spotting was 5.2 in the first cycle of use and ranged from 3.6 – 4.2 in cycles 2-13. A total of 15 subjects out of 1,677 (0.9%) discontinued the study prematurely due to metrorrhagia or irregular menstruation.

Women who are not pregnant and use GENERESS Fe may not have scheduled (withdrawal) bleeding every cycle or may experience amenorrhea (absence of any bleeding and spotting). The incidence of amenorrhea in the clinical trial increased from 8.1% of the subjects in Cycle 2 to 18.4% by Cycle 13. For those women who had scheduled (withdrawal) bleeding, the average duration of bleeding per cycle in Cycles 2-13 was 3.7 days.

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.

Some women may encounter amenorrhea or oligomenorrhea after stopping COCs, especially when such a condition was pre-existent.

5.10 COC Use Before or During Early Pregnancy

Extensive epidemiological studies have revealed no increased risk of birth defects in women who have used oral contraceptives prior to pregnancy. Studies also do not suggest a teratogenic effect, particularly in so far as cardiac anomalies and limb-reduction defects are concerned, when taken inadvertently during early pregnancy. GENERESS Fe use should be discontinued if pregnancy is confirmed.

The administration of oral contraceptives to induce withdrawal bleeding should not be used as a test for pregnancy *[see Use in Specific Populations (8.1)]*.

5.11 Depression

Women with a history of depression should be carefully observed and GENERESS Fe discontinued if depression recurs to a serious degree.

5.12 Interference with Laboratory Tests

The use of COCs may change the results of some laboratory tests, such as coagulation factors, lipids, glucose tolerance, and binding proteins. Women on thyroid hormone replacement therapy may need increased doses of thyroid hormone because serum concentrations of thyroid-binding globulin increase with use of COCs.

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 Other Conditions

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

6 ADVERSE REACTIONS

The following serious adverse reactions with the use of COCs are discussed elsewhere in the labeling:

- Serious cardiovascular events and smoking *[see Boxed Warning,* and *Warnings and Precautions (5.1)]*
- Vascular events *[see Warnings and Precautions (5.1)]*
- Liver disease *[see Warnings and Precautions (5.3)]*

Adverse reactions commonly reported by COC users are:

- 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 rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

A phase 3 clinical trial evaluated the safety and efficacy of GENERESS Fe for pregnancy prevention. The study was a multicenter, non-comparative, open-label study with a treatment duration of 12 months (thirteen 28-day cycles). A total of 1,677 women aged 18-46 were enrolled and took at least one dose of GENERESS Fe.

Adverse Reactions Leading to Study Discontinuation: 8.5% of the women discontinued from the clinical trial due to an adverse reaction. The most common adverse reactions leading to discontinuation were nausea (1.0%), weight increase (0.8%), acne (0.8%), metrorrhagia (0.7%), altered mood (0.4%), hypertension (0.4%), irritability (0.3%), migraine (0.3%), decreased libido (0.3%) and mood swings (0.3%).

Common Adverse Reactions (≥ 2% of all treated subjects): nausea/vomiting (8.8%), headaches/migraine (7.5%), depression/mood complaints (4.1%), dysmenorrhea (3.9%), acne (3.2%), anxiety symptoms (2.4%), breast pain/tenderness (2.4%), and increased weight (2.3%).

Serious Adverse Reactions: Hypertension, depression, cholecystitis, and deep vein thrombosis.

7 DRUG INTERACTIONS

No drug-drug interaction studies were conducted with GENERESS Fe.

7.1 Changes in Contraceptive Effectiveness Associated with Co-Administration of Other Products

If a woman on hormonal contraceptives takes a drug or herbal product that induces enzymes, including

CYP3A4, that metabolize contraceptive hormones, counsel her to use additional contraception or a different method of contraception. Drugs or herbal products that induce such enzymes may decrease the plasma concentrations of contraceptive hormones, and may decrease the effectiveness of hormonal contraceptives or increase breakthrough bleeding. Some drugs or herbal products that may decrease the effectiveness of hormonal contraceptives include:

- barbiturates
- bosentan
- carbamazepine
- felbamate
- griseofulvin
- oxcarbazepine
- phenytoin
- rifampin
- St. John's wort
- topiramate

HIV protease inhibitors and non-nucleoside reverse transcriptase inhibitors: Significant changes (increase or decrease) in the plasma levels of the estrogen and progestin have been noted in some cases of co-administration of HIV protease inhibitors or with non-nucleoside reverse transcriptase inhibitors.

Antibiotics: There have been reports of pregnancy while taking hormonal contraceptives and antibiotics, but clinical pharmacokinetic studies have not shown consistent effects of antibiotics on plasma concentrations of synthetic steroids.

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

7.2 Increase in Plasma Levels of Ethinyl Estradiol Associated with Co-Administered Drugs

Co-administration of atorvastatin and certain combination oral contraceptives containing ethinyl estradiol increase AUC values for ethinyl estradiol by approximately 20%. Ascorbic acid and acetaminophen may increase plasma ethinyl estradiol levels, possibly by inhibition of conjugation. CYP3A4 inhibitors such as itraconazole or ketoconazole may increase plasma hormone levels.

7.3 Concomitant Use with HCV Combination Therapy – Liver Enzyme Elevation

Do not co-administer GENERESS Fe with HCV drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, due to potential for ALT elevations [*see Warnings and Precautions (5.4)*].

7.4 Changes in Plasma Levels of Co-Administered Drugs

COCs containing some synthetic estrogens (e.g., ethinyl estradiol) may inhibit the metabolism of other compounds. COCs have been shown to significantly decrease plasma concentrations of lamotrigine, likely due to induction of lamotrigine glucuronidation. This may reduce seizure control; therefore, dosage adjustments of lamotrigine may be necessary. Consult the labeling of the concurrently-used drug to obtain further information about interactions with COCs or the potential for enzyme alterations.

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.

The administration of COCs to induce withdrawal bleeding should not be used as a test for pregnancy. COCs should not be used during pregnancy to treat threatened or habitual abortion.

Women who do not breastfeed may start COCs no earlier than four weeks postpartum.

8.3 Nursing Mothers

When possible, advise the nursing mother to use other forms of contraception until she has weaned her child. Estrogen-containing OCs 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 GENERESS Fe 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 product before menarche is not indicated.

8.5 Geriatric Use

GENERESS Fe has not been studied in postmenopausal women and is not indicated in this population.

8.6 Renal Impairment

The pharmacokinetics of GENERESS Fe have not been studied in subjects with renal impairment.

8.7 Hepatic Impairment

No studies have been conducted to evaluate the effect of hepatic disease on the disposition of GENERESS Fe. However, steroid hormones may be poorly metabolized in patients with impaired liver function. Acute or chronic disturbances of liver function may necessitate the discontinuation of COC use until markers of liver function return to normal *[see Contraindications (4),* and *Warnings and Precautions (5.3)]*.

8.8 Body Mass Index

The safety and efficacy of GENERESS Fe in women with a BMI > 35 kg/m^2 have not been evaluated.

10 OVERDOSAGE

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

11 DESCRIPTION

GENERESS Fe provides an oral contraceptive regimen consisting of 24 tablets that contain the active ingredients specified below, followed by four non-hormonal placebo tablets:

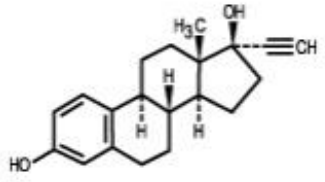
- 24 light green, round tablets each containing 0.8 mg norethindrone and 0.025 mg ethinyl estradiol
- 4 brown, round tablets each containing 75 mg ferrous fumarate

Each light green tablet also contains the following inactive ingredients: D&C Yellow No. 10 aluminum lake, FD&C Blue No. 1 aluminum lake, FD&C Yellow No. 6 aluminum lake, lactose monohydrate, magnesium stearate, mannitol, microcrystalline cellulose, povidone, sodium starch glycolate, spearmint flavor, sucralose and vitamin E.

Each brown, round tablet contains ferrous fumarate, magnesium stearate, mannitol, microcrystalline cellulose, povidone, sodium starch glycolate, spearmint flavor and sucralose. The ferrous fumarate

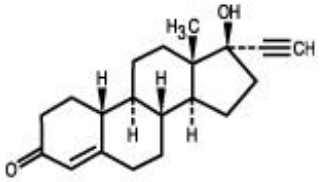
chewable tablets do not serve any therapeutic purpose. Ferrous fumarate chewable tablets are not USP for dissolution and assay.

The empirical formula of ethinyl estradiol is $C_{20}H_{24}O_2$ and the chemical structure is:



The chemical name of ethinyl estradiol is [19-Norpregna-1,3,5(10)-trien-20-yne-3,17-diol,(17α)-]

The empirical formula of norethindrone is $C_{20}H_{26}O_2$ and the chemical structure is:



The chemical name of norethindrone is [17-hydroxy-19-nor-17α-pregn-4-en-20-yn-3-one]

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 GENERESS Fe.

12.3 Pharmacokinetics

Absorption

Norethindrone and ethinyl estradiol are absorbed with maximum plasma concentrations occurring within 2 hours after GENERESS Fe administration (see Table 1). Both are subject to first-pass metabolism after oral dosing, resulting in an absolute bioavailability of approximately 64% for norethindrone and 43% for ethinyl estradiol.

The plasma norethindrone and ethinyl estradiol pharmacokinetics following single- and multiple-dose administrations of GENERESS Fe in 17 healthy female volunteers are provided in Table 1.

Following multiple-dose administration of GENERESS Fe, mean maximum concentrations of norethindrone and ethinyl estradiol were increased by 126% and 14%, respectively, as compared to single-dose administration. Mean norethindrone and ethinyl estradiol exposures (AUC values) were increased by 239% and 55% respectively, as compared to single-dose administration of GENERESS Fe.

Mean sex hormone binding globulin (SHBG) concentrations were increased by 170% from baseline (40.0 pg/mL; CV = 65%) to 108 pg/mL (CV = 45%) at steady-state.

Table 1. Pharmacokinetic Parameter Values Following Single and Multiple Dose Administration of GENERESS Fe

	Arithmetic mean parameters (%CV)				
Regimen	**Analyte**	**C_{max}**	**t_{max}**	**AUC_{0-24h}**	**$t_{1/2}$ ***
Day 1 (Single Dose) N = 17	NE	9,840 (36)	1.4 (49)	41,680 (47)	
	EE	147 (25)	1.2 (27)	903 (18)	
Day 24 (Multiple Dose) N = 17	NE	22,200 (30)	1.6 (76)	141,200 (32)	10.8
	EE	168 (25)	1.2 (35)	1,400 (32)	17.1

* The harmonic mean for $t_{1/2}$ is presented

EE = ethinyl estradiol; NE = norethindrone
%CV = coefficient of variation; C_{max} = maximum plasma concentration (pg/mL); t_{max} = time of the maximum measured plasma concentration (h); AUC_{0-24h} = area under the plasma concentration versus time curve from time 0 to 24h (pg•h/mL); $t_{1/2}$ = apparent elimination half life (h)

Food Effect

GENERESS Fe may be administered with or without food. A single-dose administration of GENERESS Fe with food decreased the maximum concentration of norethindrone by 47% and increased the extent of absorption by 10-14% and decreased the maximum concentration of ethinyl estradiol by 39% but not the extent of absorption.

Distribution

Volume of distribution of norethindrone and ethinyl estradiol ranges from 2 to 4 L/kg. Plasma protein binding of both steroids is extensive (> 95%); norethindrone binds to both albumin and SHBG, whereas ethinyl estradiol binds only to albumin. Although ethinyl estradiol does not bind to SHBG, it induces SHBG synthesis.

Metabolism

Norethindrone undergoes extensive biotransformation, primarily via reduction, followed by sulfate and glucuronide conjugation. The majority of metabolites in the circulation are sulfates, with glucuronides accounting for most of the urinary metabolites. A small amount of norethindrone is metabolically converted to ethinyl estradiol, such that exposure to ethinyl estradiol following administration of 1 mg of norethindrone acetate is equivalent to oral administration of 2.8 mcg ethinyl estradiol; therefore 0.8 mg norethindrone would be equivalent to the oral administration of 2.6 mcg ethinyl estradiol.

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, formed by the CYP3A4 isoform of cytochrome P450. Part of the first-pass metabolism of ethinyl estradiol is believed to occur in gastrointestinal mucosa. Ethinyl estradiol may undergo enterohepatic circulation.

Excretion

Norethindrone and ethinyl estradiol are excreted in both urine and feces, primarily as metabolites. Plasma clearance values for norethindrone and ethinyl estradiol are similar (approximately 0.4 L/hr/kg). Elimination half-lives of norethindrone and ethinyl estradiol following administration of 0.8 mg norethindrone / 0.025 mcg ethinyl estradiol tablets are approximately 11 hours and 17 hours, respectively.

Specific Populations

Pediatric Use: Safety and efficacy of GENERESS Fe have been established in women of reproductive age. Efficacy is expected to be the same for postpubertal adolescents under the age of 18 and for users 18 years and older. Use of this product before menarche is not indicated.

Geriatric Use: GENERESS Fe has not been studied in postmenopausal women and is not indicated in this population.

Renal Impairment: The pharmacokinetics of GENERESS Fe have not been studied in subjects with renal impairment.

Hepatic Impairment: The pharmacokinetics of GENERESS Fe have not been studied in subjects with hepatic impairment. Steroid hormones may be poorly metabolized in patients with impaired liver function. Acute or chronic disturbances of liver function may necessitate the discontinuation of COC use until markers of liver function return to normal *[see Contraindications (4),* and *Warnings and Precautions (5.3)]*.

Body Mass Index: The efficacy of GENERESS Fe in women with a BMI of > 35 kg/m^2 has not been evaluated.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

[See Warnings and Precautions (5.2, 5.3).]

14 CLINICAL STUDIES

14.1 Oral Contraceptive Clinical Trial

In a one-year (thirteen 28-day cycles) multicenter, open-label clinical trial, 1,677 women 18 to 46 years of age were studied to assess the safety and efficacy of GENERESS Fe. The ethnic origin of the 1,570 treated subjects who were evaluable for efficacy was: Caucasian (72.0%), African-American (13.0%), Hispanic (11.2%) and Asian (1.8%). The weight range was 74 to 243 pounds with a mean weight of 148.8 pounds. Of treated women, 16.2% were lost to follow-up, 8.9% discontinued by withdrawing their consent and 8.5% discontinued due to an adverse event.

The pregnancy rate (Pearl Index) in 1,251 women 18 to 35 years of age was 2.01 (95% confidence interval 1.21, 3.14) pregnancies per 100 women-years of treatment based on 19 pregnancies that occurred after onset of treatment and within 7 days after the last pill in 12,297 cycles of treatment during which no back-up contraception was used.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

GENERESS Fe is available in cartons of 3 blister cards (dispensers) (NDC 0023-6030-03).

Each blister card (28 tablets) contains in the following order:

- 24 light green, round tablets (active) imprinted with “WC” on one side and “483” on the other and each containing 0.8 mg norethindrone and 0.025 mg ethinyl estradiol.
- 4 brown, round tablets (non-hormonal placebo) imprinted with “WC” on one side and “624” on the other and each containing 75 mg ferrous fumarate.

16.2 Storage Conditions

Store at 20-25ºC (68-77ºF). [See USP controlled room temperature.]

Keep out of reach of children.

17 PATIENT COUNSELING INFORMATION

See FDA-Approved Patient Labeling

- Counsel patients that 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.
- Counsel patients that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.
- Counsel patients on Warnings and Precautions associated with COCs.
- Counsel patients to chew one tablet daily by mouth without water at the same time every day in the exact order noted on the blister. Instruct patients what to do in the event pills are missed. *See* ***What Should I Do if I Miss any Pills*** *section in* ***FDA-Approved Patient Labeling***.
- Counsel patients to use a back-up or alternative method of contraception when enzyme inducers are used with GENERESS Fe.
- Counsel patients who are breastfeeding or who desire to breastfeed that COCs may reduce breast milk production. This is less likely to occur if breastfeeding is well established.
- Counsel any patient who starts COCs postpartum, and who has not yet had a period, to use an additional method of contraception until she has taken a light green tablet for 7 consecutive days.
- Counsel patients that amenorrhea may occur. Pregnancy should be ruled out in the event of amenorrhea in two or more consecutive cycles.

For all medical inquiries contact:
Allergan USA, Inc.
Madison, NJ 07940
1-800-678-1605

Distributed By:
Allergan USA, Inc.

Madison, NJ 07940

Revised: May 2018

v.1.1USPI6030

FDA-Approved Patient Labeling

Guide for Using GENERESS Fe (norethindrone and ethinyl estradiol chewable tablets and ferrous fumarate chewable tablets)

WARNING TO WOMEN WHO SMOKE

Do not use GENERESS 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.

Birth control pills help to lower the chances of becoming pregnant when taken as directed. They do not protect against HIV infection (AIDS) and other sexually transmitted diseases.

What is GENERESS Fe?

GENERESS Fe is a birth control pill. It contains two female hormones, an estrogen called ethinyl estradiol and a progestin called norethindrone.

How Do I Take GENERESS Fe?

- Chew and swallow one pill every day without water at the same time. Take the pills in the order

directed on the blister pack.

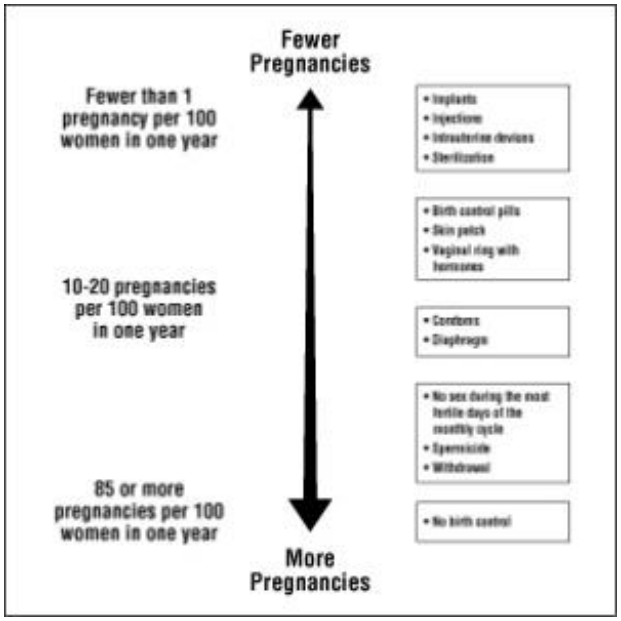
- Do not skip pills or take at intervals exceeding 24 hours. If you miss pills (including starting the pack late), you could get pregnant. The more pills you miss, the more likely you are to get pregnant.
- If you have trouble remembering to take GENERESS Fe, talk to your healthcare provider about how to make pill taking easier or about using another method of birth control.
- You may have spotting or light bleeding when you first take GENERESS Fe. Spotting or light bleeding is normal at first.
- You may feel sick to your stomach (nauseated), especially during the first few months that you take GENERESS Fe. If you feel sick to your stomach, do not stop taking the pill. The problem will usually go away. If your nausea doesn't go away, call your healthcare provider.
- If you vomit or have diarrhea within 3-4 hours of taking your pill, follow the instructions for "What Should I Do if I Miss any Pills."
- Missing pills can also cause spotting or light bleeding, even when you take the missed pills late. On the days you take 2 pills to make up for missed pills, you could also feel a little sick to your stomach.

How Well Does GENERESS Fe Work?

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

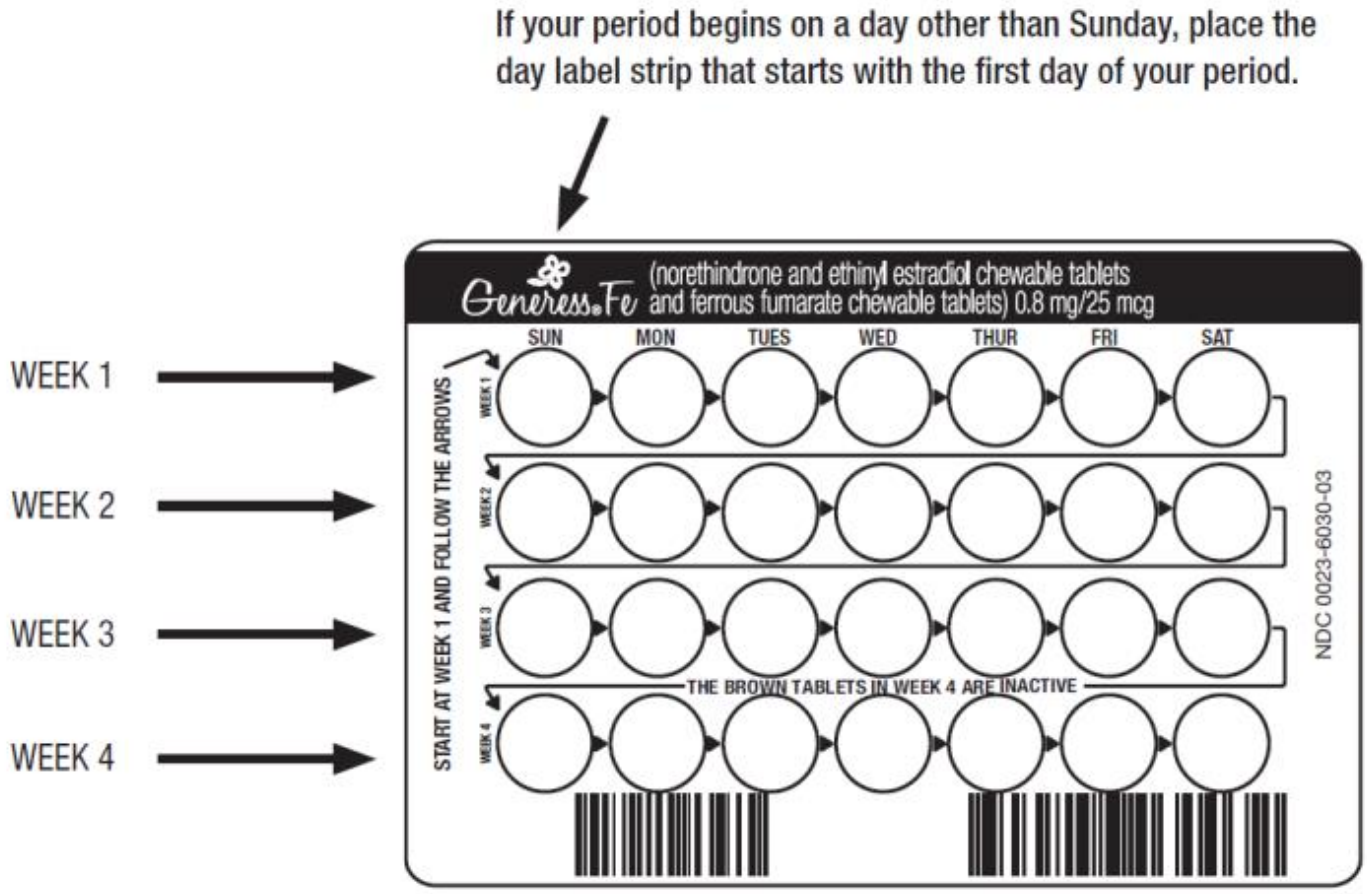
Based on the results of one clinical study, 1 to 3 women out of 100 women may get pregnant during the first year they use GENERESS Fe.

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.



Before you start taking GENERESS Fe

- Decide what time of day to take your pill. It is important to take it at the same time every day and in the order as directed on the blister pack.



- Look at your GENERESS Fe blister pack. The blister pack has four rows of 7 pills each, for a total of 28 pills. Find:
  - where on the pack to start taking your pills
  - in what order to take the pills

Each GENERESS Fe blister pack has 28 pills

- 24 light green pills with hormones for Weeks 1, 2 and 3 and the first part of Week 4
- 4 brown pills without hormones for the remainder of Week 4

- Be sure to have ready at all times another kind of birth control (such as a condom and spermicide) to use as a back-up in case you miss pills.

When to Start GENERESS Fe

If you start taking GENERESS Fe and you did not use a hormonal birth control method before:

DAY-1 START:

- Pick the day label strip that starts with the first day of your period (this is the day you start bleeding or spotting, even if it is almost midnight when the bleeding begins). Pick a time of day that will be easy to remember.
- Place this day label strip on the tablet dispenser over the area that has the days of the week (starting with Sunday) printed on the plastic.
- Take the first light green pill of the first pack during the first 24 hours of your period.
- You will not need to use a back-up method of birth control because you are starting the pill at the beginning of your period. However, if you start on a day other than the first day of your period or if you are starting after having been pregnant and have not yet had a period, use a back-up method of birth control such as a condom and spermicide until you have taken a light green pill for *7 days* in a row.
- After taking the last brown pill (day 28) of the blister pack, start taking the first light green pill from

a new blister pack the very next day whether or not you are having your period.

If you start taking GENERESS Fe and you are switching from a combination hormonal method such as:

- another pill
- vaginal ring
- patch

- Take the first light green pill on the first day you would have started your previous birth control pack.
- If you previously used a vaginal ring or transdermal patch, finish the 21 days of use and wait *7 days* after removal of the ring or transdermal patch before starting GENERESS Fe.
- Use a non-hormonal back-up method such as a condom and spermicide for the first *7 days* you take GENERESS Fe.

If you start taking GENERESS Fe and you are switching from a progestin-only method such as a:

- progestin-only pill
- implant
- intrauterine system
- injection

- Take the first light green pill on the day you would have taken your next progestin-only pill or on the day of removal of your implant or intrauterine system or on the day when you would have had your next injection.
- Use a non-hormonal back-up method such as a condom and spermicide for the first *7 days* you take GENERESS Fe.

What Should I do if I Miss any Pills

If you forgot to start a new blister pack, **you may already be pregnant**. Use back-up contraception (such as a condom and spermicide) anytime you have sex. Call your healthcare provider if you are unsure whether you are pregnant.

Your birth control pills may not be as effective if you miss any light green pills, and particularly if you miss the first few or the last few light green pills in a pack.

If you MISS ONE light green pill

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

If you MISS TWO light green pills in a row in WEEK 1 or WEEK 2 of your pack

- Take two pills on the day you remember and two pills the next day.
- Then take one pill a day until you finish the pack.
- You could become pregnant if you have sex during the *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 for those *7 days*.

If you MISS TWO light green pills in a row in WEEK 3 or WEEK 4 of your pack

- THROW OUT the rest of the pill pack and start a new pack that same day.
- You could become pregnant if you have sex during the *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 for those *7 days* after you restart your pills.

If you MISS THREE OR MORE light green pills in a row at any time

- THROW OUT the rest of the pill pack and start a new pack that same day.

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

If you forget any of the four brown "reminder" pills in WEEK 4

- THROW AWAY the pills you missed.
- Keep taking one pill each day until the pack is finished.
- You do not need to use a back-up method of birth control.

You may already be pregnant or COULD BECOME PREGNANT if you had sex on the days after the pills were missed. The more pills missed and the closer they are to the end of the cycle, the higher the risk of a pregnancy. You should call your doctor or healthcare provider if you are unsure whether you are already pregnant.

If you are still not sure of what to do about the pills you have missed:

- Call your healthcare provider.
- Use a back-up contraception (such as a condom and spermicide) anytime you have sex and keep taking 1 pill each day.

Who Should not Take GENERESS Fe?

Your healthcare provider will not give you GENERESS Fe if you have:

- Ever had breast cancer or any cancer that is sensitive to female hormones
- Liver disease, 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.
- Ever had blood clots in your arms, legs, or lungs
- Ever had a stroke
- Ever had a heart attack
- Certain heart valve problems or heart rhythm abnormalities that can cause blood clots to form in the heart
- An inherited problem with your blood that makes it clot more than normal
- High blood pressure that medicine can't control
- Diabetes with kidney, eye, or blood vessel damage
- Certain kinds of severe migraine headaches with aura, numbness, weakness or changes in vision

Also, do not take birth control pills if you:

- Smoke and are over 35 years old
- Are pregnant

Birth control pills may not be a good choice for you if you have ever had jaundice (yellowing of the skin or eyes) caused by pregnancy (also called cholestasis of pregnancy).

What Else Should I Know about Taking GENERESS Fe?

Birth control pills do not protect you against any sexually transmitted disease, including HIV, the virus that causes AIDS.

Do not skip any pills, even if you do not have sex often.

If you miss a period, you could be pregnant. However, some women miss periods or have light periods on birth control pills, even when they are not pregnant. Contact your healthcare provider for advice if

you:

- Think you are pregnant
- Miss one period and have not taken your birth control pills according to directions
- Miss two periods in a row

Birth control pills should not be taken during pregnancy. However, birth control pills taken by accident during pregnancy are not known to cause birth defects.

You should stop GENERESS Fe at least four weeks before you have major surgery and not restart it until at least two weeks after the surgery due to an increased risk of blood clots.

If you are breastfeeding, consider another birth control method until you are ready to stop breastfeeding. Birth control pills that contain estrogen, like GENERESS Fe, may decrease the amount of milk you make. A small amount of the pill's hormones pass into breast milk.

Tell your healthcare provider about all medicines and herbal products that you take. Some medicines and herbal products may make birth control pills less effective, including:

- barbiturates
- bosentan
- carbamazepine
- felbamate
- griseofulvin
- oxcarbazepine
- phenytoin
- rifampin
- St. John’s wort
- topiramate

Consider using another birth control method when you take medicines that may make birth control pills less effective.

Birth control pills may interact with lamotrigine, an anticonvulsant used for epilepsy. This may increase the risk of seizures, so your healthcare provider may need to adjust the dose of lamotrigine.

If you have vomiting or diarrhea, your birth control pills may not work as well. Use another birth control method, like a condom and spermicide, until you check with your healthcare provider.

What are the Most Serious Risks of Taking Birth Control Pills?

Like pregnancy, birth control pills increase the risk of serious blood clots, especially in women who have other risk factors, such as smoking, obesity, or age greater than 35. It is possible to die from a problem caused by a blood clot, such as a heart attack or a stroke. Some examples of serious blood clots are blood clots in the:

- Legs (thrombophlebitis)
- Lungs (pulmonary embolus)
- Eyes (loss of eyesight)
- Heart (heart attack)
- Brain (stroke)

A few women who take birth control pills may get:

- High blood pressure
- Gallbladder problems
- Rare cancerous or noncancerous liver tumors

All of these events are uncommon in healthy women.

Call your healthcare provider right away if you have:

- Persistent leg pain
- Sudden shortness of breath
- Sudden blindness, partial or complete
- Severe pain in your chest
- Sudden, severe headache unlike your usual headaches
- Weakness or numbness in an arm or leg, or trouble speaking
- Yellowing of the skin or eyeballs

What are the Common Side Effects of Birth Control Pills?

The most common side effects of birth control pills are:
- Spotting or bleeding between menstrual periods
- Nausea
- Breast tenderness
- Headache

These side effects are usually mild and usually disappear with time.

Less common side effects are:
- Acne
- Less sexual desire
- Bloating or fluid retention
- Blotchy darkening of the skin, especially on the face
- High blood sugar, especially in women who already have diabetes
- High fat levels in the blood
- Depression, especially if you have had depression in the past. Call your healthcare provider immediately if you have any thoughts of harming yourself.
- Problems tolerating contact lenses
- Weight changes

This is not a complete list of possible side effects. Talk to your healthcare provider if you develop any side effects that concern you. You may report side effects to the FDA at 1-800-FDA-1088.

No serious problems have been reported from a birth control pill overdose, even when accidentally taken by children.

Do Birth Control Pills Cause Cancer?

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

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

What Should I Know about My Period when Taking GENERESS Fe?

Unscheduled (irregular) vaginal bleeding or spotting may occur while you are taking GENERESS Fe. Unscheduled bleeding may vary from slight staining to breakthrough bleeding, which is a flow much like a regular period, but which occurs between menstrual periods. Unscheduled bleeding occurs most often during the first few months of oral contraceptive use, but may also occur after you have been taking the pill for some time. Such bleeding may be temporary and usually does not indicate any serious problems.

Approximately one-third of the women who use GENERESS Fe have unscheduled bleeding or spotting in the first months of use. About one-quarter of users continue to have unscheduled bleeding or spotting after one year of use.

It is important to continue taking your pills on schedule. If the bleeding occurs in more than one cycle, is

unusually heavy, or lasts for more than a few days, call your healthcare provider.

What if I Miss My Scheduled Period when Taking GENERESS Fe?

Women who use GENERESS Fe may not have a period at the end of every 28-day pack of pills.

If you miss more than two periods in a row or miss one period when you have not taken your birth control pills according to directions, call your healthcare provider. Also notify your healthcare provider if you have symptoms of pregnancy such as morning sickness or unusual breast tenderness. It is important that your healthcare provider checks you to find out if you are pregnant. Stop taking GENERESS Fe if you are pregnant.

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.

General Advice about GENERESS Fe

Your healthcare provider prescribed GENERESS Fe for you. Please do not share GENERESS Fe with anyone else. Keep GENERESS Fe out of the reach of children.

If you have concerns or questions, ask your healthcare provider. You may also ask your healthcare provider for a more detailed label written for medical professionals.

For more information, go to www.generess.com or you can contact Allergan at 1-800-678-1605.

For all medical inquiries contact:
Allergan USA, Inc.
Madison, NJ 07940
1-800-678-1605

Distributed By:
Allergan USA, Inc.

Madison, NJ 07940

Revised: May 2018

V.1.PPI6030

PRINCIPAL DISPLAY PANEL

Generess® Fe
(norethindrone and ethinyl estradiol chewable tablets
and ferrous fumarate chewable tablets) 0.8 mg/25 mcg
NDC 52544-204-31
Carton x Three 28-Tablet Dispensers

GENERESS FE

norethindrone and ethinyl estradiol and ferrous fumarate kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0023-6030

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0023-6030-03	3 in 1 CARTON	12/23/2011	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1		24
Part 2		4

Part 1 of 2

GENERESS FE

norethindrone and ethinyl estradiol and ferrous fumarate tablet

Product Information	
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
NORETHINDRONE (UNII: T18F433X4S) (NORETHINDRONE - UNII:T18F433X4S)	NORETHINDRONE	0.8 mg
ETHINYL ESTRADIOL (UNII: 423D2T571U) (ETHINYL ESTRADIOL - UNII:423D2T571U)	ETHINYL ESTRADIOL	0.025 mg

Inactive Ingredients	
Ingredient Name	**Strength**
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SPEARMINT (UNII: J7I2T6IV1N)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	

Product Characteristics			
Color	GREEN	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor	SPEARMINT	**Imprint Code**	WC;483
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022573	12/22/2010	

Part 2 of 2

GENERESS FE

norethindrone and ethinyl estradiol and ferrous fumarate tablet

Product Information	
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	75 mg

Inactive Ingredients	
Ingredient Name	**Strength**
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SPEARMINT (UNII: J7I2T6IV1N)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color	BROWN	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor	SPEARMINT	**Imprint Code**	WC;624
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022573	12/22/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022573	12/23/2011	

Labeler - Allergan, Inc. (144796497)

Revised: 5/2018 Allergan, Inc.