FINZALA- norethindrone acetate and ethinyl estradiol and ferrous fumarate
Teva Pharmaceuticals USA, Inc.

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

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

WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS

See full prescribing information for complete boxed warning.

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

INDICATIONS AND USAGE

- Finzala is a combination of norethindrone acetate, a progestin, and ethinyl estradiol, an estrogen, indicated for use by females of reproductive potential to prevent pregnancy (1)
- The efficacy in females of reproductive potential with a body mass index of more than 35 kg/m^2 has not been evaluated (1, 8.8)

DOSAGE AND ADMINISTRATION

- One tablet daily chewed and swallowed or swallowed whole taken at the same time of day. Follow with 8 ounces of water (2.1)
- Take one tablet by mouth at the same time every day for 28 days (2.1)
- Take tablets in the order directed on the blister pack (2.1)
- Tablets may be administered without regard to meals (12.3)

DOSAGE FORMS AND STRENGTHS

Finzala® (norethindrone acetate and ethinyl estradiol tablets, 1 mg/20 mcg and ferrous fumarate tablets) consist of 28 tablets in the following order (3):

- 24 white chewable tablets (active), each containing 1 mg norethindrone acetate and 20 mcg ethinyl estradiol
- 4 brown tablets (non-hormonal placebo), each containing 75 mg ferrous fumarate, which do not serve any therapeutic purpose

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

- Vascular risks: Stop Finzala if a thrombotic event occurs. Stop at least 4 weeks before through 2 weeks after major surgery. Start no earlier than 4 weeks after delivery, in women who are not breastfeeding (5.1)
- Liver disease: Discontinue if jaundice occurs (5.2)
- High blood pressure: Do not prescribe for women with uncontrolled hypertension or hypertension with vascular disease (5.4)
- Carbohydrate and lipid metabolic effects: Monitor prediabetic and diabetic women taking Finzala. Consider an alternative contraceptive method for women with uncontrolled dyslipidemia (5.6)
- Headache: Evaluate significant change in headaches and discontinue if indicated (5.7)
- Uterine bleeding: Evaluate irregular bleeding or amenorrhea (5.8)

ADVERSE REACTIONS

- The most common adverse reactions in clinical trials (greater than or equal to 2%) were: headache, vaginal candidiasis, nausea, menstrual cramps, breast tenderness, bacterial vaginitis, abnormal cervical smear, acne, mood swings, and weight gain. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Teva at 1-888-838-2872 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

- Lactation: Not recommended; can decrease milk production (8.2)

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

Revised: 9/2024

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) and Warnings and Precautions (5.1)].*

1 INDICATIONS AND USAGE

- Finzala is indicated for use by females of reproductive age to prevent pregnancy *[see Clinical Studies (14)]*.
- The efficacy of Finzala in women with a body mass index (BMI) of more than 35 kg/m^2 has not been evaluated.

2 DOSAGE AND ADMINISTRATION

2.1 How to Take Finzala

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

2.2 How to Start Finzala

Instruct the patient to begin taking Finzala either on the first day of her menstrual period (Day 1 Start) or on the first Sunday after the onset of her menstrual period (Sunday Start).

Day 1 Start

During the first cycle of Finzala use, instruct the patient to take one white Finzala tablet daily, beginning on Day one (1) of her menstrual cycle (the first day of menstruation is Day one). She should take one white Finzala tablet daily for 24 consecutive days, followed by one brown tablet daily on days 25 through 28. Finzala should be taken in the order directed on the package at the same time each day. Instruct the patient to use a non-hormonal contraceptive as back-up during the first 7 days if she starts taking Finzala on a day other than the first day of her menstrual cycle. The possibility of ovulation and conception prior to initiation of medication should be considered.

Sunday Start

During the first cycle of Finzala use, instruct the patient to take one white Finzala tablet daily, beginning on the first Sunday after the onset of her menstrual period. She should take one white Finzala tablet daily for 24 consecutive days, followed by one brown tablet daily on days 25 through 28. Finzala should be taken in the order directed on the package at the same time each day. Finzala should not be considered effective as a contraceptive until after the first 7 consecutive days of product administration. Instruct the patient to use a non-hormonal contraceptive as back-up during the first 7 days. The possibility of ovulation and conception prior to initiation of medication should be considered.

The patient should begin her next and all subsequent 28-day regimens of Finzala on the same day of the week that she began her first regimen, following the same schedule. She should begin taking her white Finzala tablets on the next day after ingestion of the last brown tablet, regardless of whether or not a menstrual period has occurred or is still in progress. Anytime a subsequent cycle of Finzala is started later than the day following administration of the last brown tablet, the patient should use another method of contraception until she has taken a white Finzala tablet daily for 7 consecutive days.

For postpartum women who do not breastfeed or after a second trimester abortion, start Finzala no earlier than 4 weeks postpartum due to the increased risk of thromboembolism. If the patient starts on Finzala postpartum and has not yet had a period, evaluate for possible pregnancy, and instruct her to use an additional method of contraception until she has taken Finzala for 7 consecutive days.

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

Switching from another Hormonal Method of Contraception

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

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

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

- She may switch any day from a progestin-only pill; instruct her to take the first white Finzala tablet on the day she would have taken her next progestin-only pill. She should use a non-hormonal method of contraception for 7 consecutive days.
- If switching from an implant or injection, start the first white Finzala tablet on the day her next injection would have been due or on the day of removal of her implant.
- If switching from an IUD, depending on the timing of removal, back-up contraception may be needed.

2.3 Missed Doses

Table 1. Instructions for Missed Finzala Tablets

If one white tablet is missed	Take the missed tablet as soon as possible. Take the next tablet at the regular time. Continue taking one tablet a day until the pack is finished. Additional nonhormonal contraception (such as condoms) is not needed.
If two white tablets in a row are missed in Week 1 or Week 2 of the tablet pack	Take the two missed tablets as soon as possible, and the next two tablets the next day. Continue taking one tablet a day until the pack is finished. Use additional nonhormonal contraception (such as condoms) until hormonal tablets have been taken for 7 days after missing tablets.
If two white tablets are missed in Week 3 or Week 4 of the tablet pack	**Day 1 Starter:** Throw out the rest of the tablet pack and start a new pack that same day. **Sunday Starter:** Keep taking one tablet every day until Sunday. On Sunday, throw out the rest of the pack and start a new pack of tablets that same day. Use additional nonhormonal contraception (such as condoms) until hormonal tablets have been taken for 7 days after missing tablets.
If three or more white tablets in a row are missed	**Day 1 Starter:** Throw out the rest of the tablet pack and start a new pack that same day. **Sunday Starter:** Keep taking one tablet every day until Sunday. On Sunday, throw out the rest of the pack and start a new pack of tablets that same day. Bleeding may occur during the week following the missed tablets. Use additional nonhormonal contraception (such as condoms) until hormonal tablets have been taken for 7 days after missing tablets.
If any of the four brown tablets are missed	Throw away the missed tablets. Continue taking the remaining tablets until the pack is finished. Additional nonhormonal contraception (such as condoms) is not needed.

2.4 Advice in Case of Gastrointestinal Disturbances

If the patient vomits or has diarrhea (within 3 to 4 hours after she takes a white Finzala tablet), she should follow the instructions in the "What to Do if You Miss Tablets" section *[see 2.3 Missed Doses]*.

3 DOSAGE FORMS AND STRENGTHS

Finzala® (norethindrone acetate and ethinyl estradiol tablets USP, 1 mg/20 mcg and ferrous fumarate tablets) is available in blister packs.

Each blister pack contains 28 tablets in the following order:

- 24 white, round, flat-faced, beveled-edge, unscored (active) chewable tablets debossed with **E24** on one side and **TV** on the other side, and each containing 1 mg norethindrone acetate, USP and 20 mcg ethinyl estradiol, USP.
- 4 brown, round, flat-faced, beveled-edge, unscored (non-hormonal placebo) tablets debossed with **F75** on one side and **TV** on the other side, and each containing 75 mg ferrous fumarate, USP. The ferrous fumarate tablets do not serve any therapeutic purpose.

4 CONTRAINDICATIONS

Finzala 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:
  - Smoke, if over age 35 *[see Boxed Warning and Warnings and Precautions (5.1)]*
  - Have deep vein thrombosis or pulmonary embolism, now or in the past *[see Warnings and Precautions (5.1)]*
  - Have cerebrovascular disease *[see Warnings and Precautions (5.1)]*
  - Have coronary artery disease *[see Warnings and Precautions (5.1)]*
  - Have thrombogenic valvular or thrombogenic rhythm diseases of the heart (for example, subacute bacterial endocarditis with valvular disease, or atrial fibrillation) *[see Warnings and Precautions (5.1)]*
  - Have inherited or acquired hypercoagulopathies *[see Warnings and Precautions (5.1)]*
  - Have uncontrolled hypertension *[see Warnings and Precautions (5.4)]*
  - Have diabetes mellitus with vascular disease *[see Warnings and Precautions (5.5)]*
  - Have headaches with focal neurological symptoms or have migraine headaches with aura
    - All women over age 35 with migraine headache *[see Warnings and Precautions (5.6)]*
- Liver tumors, benign or malignant, or liver disease *[see Warnings and Precautions (5.2)]*
- Undiagnosed abnormal uterine bleeding *[see Warnings and Precautions (5.7)]*
- Current diagnosis of, or history of, breast cancer, which may be hormone-sensitive *[see Warnings and Precautions (5.10)]*
- Use of Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, due to the potential for ALT elevations *[see Warnings and Precautions (5.3)]*

5 WARNINGS AND PRECAUTIONS

5.1 Thromboembolic Disorders and Other Vascular Problems

Stop norethindrone acetate and ethinyl estradiol tablets and ferrous fumarate tablets if an arterial or deep venous thrombotic event (VTE) occurs. Stop norethindrone acetate and ethinyl estradiol tablets and ferrous fumarate tablets if there is unexplained loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions. Evaluate for retinal vein thrombosis immediately.

If feasible, stop norethindrone acetate and ethinyl estradiol tablets and ferrous fumarate tablets at least 4 weeks before and through 2 weeks after major surgery or other surgeries known to have an elevated risk of VTE.

Start norethindrone acetate and ethinyl estradiol tablets and ferrous fumarate tablets 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 a COC. The risk of thromboembolic disease due to oral contraceptives gradually disappears after COC 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), although, in general, the risk is greatest in older (greater than 35 years of age), hypertensive women who also smoke. COCs also increase the risk for stroke in women with underlying risk factors.

Use COCs with caution in women with cardiovascular disease risk factors.

5.2 Liver Disease

Impaired Liver Function

Do not use norethindrone acetate and ethinyl estradiol tablets and ferrous fumarate tablets in women with acute viral hepatitis or severe (decompensated) cirrhosis of the 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 acetate and ethinyl estradiol tablets and ferrous fumarate tablets if jaundice develops.

Liver Tumors

Norethindrone acetate and ethinyl estradiol tablets and ferrous fumarate tablets 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 per 100,000 COC users. Rupture of hepatic adenomas may cause death through intra-abdominal hemorrhage.

Studies have shown an increased risk of developing hepatocellular carcinoma in long-term (greater than 8 years) COC users. However, the attributable 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 acetate and ethinyl estradiol tablets and ferrous fumarate tablets prior to starting therapy with the combination drug regimen ombitasvir/paritaprevir/ritonavir, with or without dasabuvir *[see Contraindications (4)]*. Norethindrone acetate and ethinyl estradiol tablets and ferrous fumarate tablets can be restarted approximately 2 weeks following completion of treatment with the Hepatitis C combination drug regimen.

5.4 High Blood Pressure

Norethindrone acetate and ethinyl estradiol tablets and ferrous fumarate tablets 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 acetate and ethinyl estradiol tablets and ferrous fumarate tablets 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 also 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 are taking norethindrone acetate and ethinyl estradiol tablets and ferrous fumarate tablets. COCs may decrease glucose tolerance in a dose-related fashion.

Consider alternative contraception for women with uncontrolled dyslipidemias. A small

proportion of women will have adverse lipid changes while on COCs.

Women with hypertriglyceridemia, or a family history thereof, may be at an increased risk of pancreatitis when using COCs.

5.7 Headache

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

Consider discontinuation of norethindrone acetate and ethinyl estradiol tablets and ferrous fumarate tablets in the case of increased frequency or severity of migraine during COC use (which may be prodromal of a cerebrovascular event) *[see Contraindications (4)]*.

5.8 Bleeding Irregularities and Amenorrhea

Unscheduled Bleeding and Spotting

Unscheduled (breakthrough or intracyclic) bleeding and spotting sometimes occur in patients on COCs, especially during the first three months of use. If bleeding persists or occurs after previously regular cycles, check for causes such as pregnancy or malignancy. If pathology and pregnancy are excluded, bleeding irregularities may resolve over time or with a change to a different COC.

Based on patient diaries from a clinical trial evaluating the safety and efficacy of a 24-day regimen of norethindrone acetate 1 mg/ethinyl estradiol 20 mcg tablets, 24% to 35% of women experienced unscheduled bleeding per cycle. A total of 10 subjects out of 743 (1.3%) discontinued due to bleeding or spotting.

Amenorrhea and Oligomenorrhea

Women who are not pregnant and use norethindrone acetate and ethinyl estradiol tablets and ferrous fumarate tablets may experience amenorrhea. In the clinical trial with a 24-day regimen of norethindrone acetate 1 mg/ethinyl estradiol 20 mcg tablets and ferrous fumarate tablets, 22% to 36% of the women using norethindrone acetate 1 mg/ethinyl estradiol 20 mcg tablets and ferrous fumarate tablets experienced amenorrhea in at least one of 6 cycles of use. Some women may experience post-pill amenorrhea or oligomenorrhea, 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 acetate and ethinyl estradiol tablets and ferrous fumarate tablets if pregnancy is confirmed.

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

5.10 Depression

Carefully observe women with a history of depression and discontinue norethindrone acetate and ethinyl estradiol tablets and ferrous fumarate tablets if depression recurs to a serious degree.

5.11 Malignant Neoplasms

Breast Cancer

Norethindrone acetate and ethinyl estradiol tablets and ferrous fumarate tablets 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 Adverse Reactions (6.2)]*.

Cervical Cancer

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

5.12 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 hormones 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 acetate and ethinyl estradiol tablets and ferrous fumarate tablets.

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)]*

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

The data presented in Section 6.1 are from a clinical trial conducted with a 24-day regimen of norethindrone acetate 1 mg/ethinyl estradiol 20 mcg tablets. Norethindrone acetate and ethinyl estradiol tablets are bioequivalent to these norethindrone acetate/ethinyl estradiol tablets.

Common Adverse Reactions (Greater Than or Equal to 2% of all Treated Subjects): The most common adverse reactions reported by at least 2% of the 743 women using norethindrone acetate/ethinyl estradiol tablets were the following, in order of decreasing incidence: headache (6.3%), vaginal candidiasis (6.1%), nausea (4.6%), menstrual cramps (4.4%), breast tenderness (3.4%), bacterial vaginitis (3.1%), abnormal cervical smear (3.1%), acne (2.7%), mood swings (2.2%), and weight gain (2.0%).

Adverse Reactions Leading to Study Discontinuation: Among the 743 women using norethindrone acetate/ethinyl estradiol tablets, 46 women (6.2%) withdrew because of an adverse event. Adverse events occurring in 3 or more subjects leading to discontinuation of treatment were, in decreasing order: abnormal or irregular bleeding (1.3%), nausea (0.8%), menstrual cramps (0.5%), and increased blood pressure (0.4%).

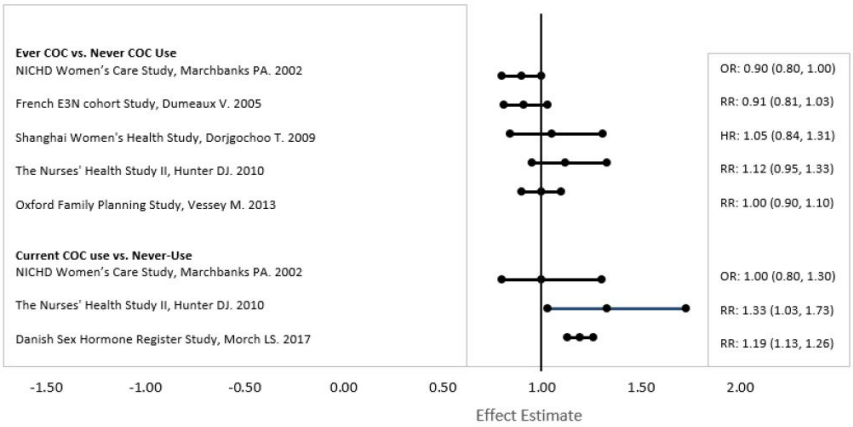
6.2 Postmarketing Experience

Five studies that compared breast cancer risk between ever-users (current or past use)

of COCs and never-users of COCs reported no association between ever use of COCs and breast cancer risk, with effect estimates ranging from 0.90 to 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 to 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 to 10 years of COC use.

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



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

The following adverse reactions have been identified during post approval use of a 24-day regimen of norethindrone acetate 1 mg/ethinyl estradiol 20 mcg tablets. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or evaluate a causal relationship to drug exposure.

Adverse reactions are grouped into System Organ Classes.

Vascular disorders: thrombosis/embolism (coronary artery, pulmonary, cerebral, deep vein).

Hepatobiliary disorders: cholelithiasis, cholecystitis, hepatic adenoma, hemangioma of liver.

Immune system disorders: hypersensitivity reaction.

Skin and subcutaneous disorders: alopecia, rash (generalized and allergic), pruritus, skin discoloration.

GI disorders: nausea, vomiting, abdominal pain.

Musculoskeletal and connective tissue disorders: myalgia.

Eye disorders: blurred vision, visual impairment, corneal thinning, change in corneal curvature (steepening).

Infections and infestations: fungal infection, vaginal infection.

Investigations: change in weight or appetite (increase or decrease), fatigue, malaise, peripheral edema, blood pressure increased.

Nervous system disorders: headache, dizziness, migraine, loss of consciousness.

Psychiatric disorders: mood swings, depression, insomnia, anxiety, suicidal ideation, panic attack, changes in libido.

Renal and urinary disorders: cystitis-like syndrome.

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

Cardiovascular: chest pain, palpitations, tachycardia, myocardial infarction.

7 DRUG INTERACTIONS

Consult the labeling of the concurrently-used drug to obtain further information about

interactions with COCs or the potential for enzyme alterations.

No drug-drug interaction studies were conducted with norethindrone acetate and ethinyl estradiol tablets and ferrous fumarate tablets.

7.1 Effects of Other Drugs on Combined Oral Contraceptives

Substances diminishing the efficacy of COCs: Drugs or herbal products that induce certain enzymes, including cytochrome P450 3A4 (CYP3A4), may decrease 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 and products containing St. John's wort. Interactions between oral contraceptives and other drugs may lead to breakthrough bleeding and/or contraceptive failure. Counsel women to use 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.

Substances increasing the plasma concentrations of COCs: Coadministration of atorvastatin and certain COCs containing ethinyl estradiol increase AUC values for ethinyl estradiol by approximately 20%. Ascorbic acid and acetaminophen may increase plasma ethinyl estradiol concentrations, possibly by inhibition of conjugation. CYP3A4 inhibitors such as itraconazole 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 the estrogen and progestin have been noted in some cases of coadministration of HIV/HCV protease inhibitors or of 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.

7.2 Effects of Combined Oral Contraceptives on Other Drugs

COCs containing 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.

Women on thyroid hormone replacement therapy may need increased doses of thyroid hormone because serum concentration of thyroid-binding globulin increases with use of COCs.

7.3 Concomitant Use with HCV Combination Therapy – Liver Enzyme Elevation

Do not coadminister norethindrone acetate and ethinyl estradiol tablets and ferrous fumarate tablets 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

Risk Summary

There is no use for contraception in pregnancy; therefore, norethindrone acetate and ethinyl estradiol tablets and ferrous fumarate tablets should be discontinued during 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 COCs before conception or during early pregnancy.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4 percent and 15 to 20 percent, respectively.

8.2 Lactation

Risk Summary

Contraceptive hormones and/or metabolites are present in human milk. COCs can reduce milk production in breastfeeding females. This reduction can occur at any time but is less likely to occur once breastfeeding is well-established. When possible, advise the nursing female to use other methods of contraception until she discontinues breastfeeding *[see Dosage and Administration (2.2)]*. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for norethindrone acetate and ethinyl estradiol tablets and ferrous fumarate tablets and any potential adverse effects on the breastfed child from norethindrone acetate and ethinyl estradiol tablets and ferrous fumarate tablets or from the underlying maternal condition.

8.4 Pediatric Use

Safety and efficacy of norethindrone acetate and ethinyl estradiol tablets and ferrous fumarate tablets 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

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

8.6 Renal Impairment

The pharmacokinetics of norethindrone acetate and ethinyl estradiol tablets and ferrous fumarate tablets has not been studied in subjects with renal impairment.

8.7 Hepatic Impairment

The pharmacokinetics of norethindrone acetate and ethinyl estradiol tablets and ferrous fumarate tablets has not been studied in subjects with hepatic impairment. However, steroid hormones may be poorly metabolized in patients with hepatic impairment. Acute or chronic disturbances of liver function may necessitate the discontinuation of COC use until markers of liver function return to normal and COC causation has been excluded *[see Contraindications (4) and Warnings and Precautions (5.2)].*

8.8 Body Mass Index

The safety and efficacy of norethindrone acetate and ethinyl estradiol tablets and ferrous fumarate tablets in women with a body mass index (BMI) greater than 35 kg/m^2 has not been evaluated *[see Clinical Studies (14)]*.

10 OVERDOSAGE

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

11 DESCRIPTION

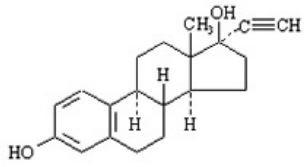
Finzala® (norethindrone acetate and ethinyl estradiol tablets USP, 1 mg/20 mcg and ferrous fumarate tablets) provide an oral contraceptive regimen consisting of 24 white active chewable tablets that contain the active ingredients, followed by 4 brown non-hormonal placebo tablets as specified below:

- 24 white, round, flat-faced, beveled-edge, unscored tablets each containing 1 mg norethindrone acetate, USP and 20 mcg ethinyl estradiol, USP.
- 4 brown, round, flat-faced, beveled-edge, unscored tablets each containing 75 mg ferrous fumarate, USP.

Each white active chewable tablet also contains the following inactive ingredients: acacia, confectioner's sugar, lactose monohydrate, magnesium stearate, maltodextrin, pregelatinized corn starch, silicon dioxide, spearmint oil, sucralose, and talc.

Each brown placebo tablet contains ferrous fumarate USP, magnesium stearate, maltodextrin, mannitol, microcrystalline cellulose, povidone, sodium starch glycolate type A, silicon dioxide, spearmint oil, and sucralose. The ferrous fumarate tablets do not serve any therapeutic purpose. Ferrous fumarate tablets are not USP for dissolution and assay.

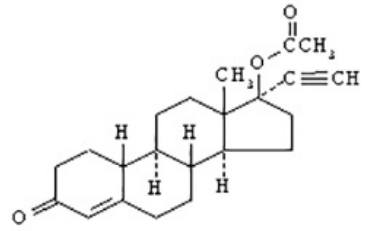
The structural formula of ethinyl estradiol, USP is:



$C_{20}H_{24}O_2$ MW: 296.40

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

The structural formula of norethindrone acetate, USP is:



$C_{22}H_{28}O_3$ MW: 340.46

The chemical name of norethindrone acetate, USP is [19-Norpregn-4-en-20-yn-3-one, 17-(acetyloxy)-, (17α)-].

FDA approved dissolution test specifications differ from USP.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

CHCs lower the risk of becoming pregnant primarily by suppressing ovulation.

12.2 Pharmacodynamics

No specific pharmacodynamic studies were conducted with Finzala.

12.3 Pharmacokinetics

Absorption

In a single-dose, two-way, crossover clinical study conducted in 35 healthy, non-smoking premenopausal women under fasting condition, norethindrone acetate and ethinyl estradiol tablets chewed and swallowed were bioequivalent to norethindrone acetate 1 mg/ethinyl estradiol 20 mcg tablets (24-day regimen tablets) swallowed whole based on the exposure (AUC) and peak concentration (C_{max}) of norethindrone and ethinyl estradiol.

Norethindrone acetate appears to be completely and rapidly deacetylated to norethindrone after oral administration, because the disposition of norethindrone acetate is indistinguishable from that of orally administered norethindrone. Norethindrone acetate and ethinyl estradiol are absorbed from Finzala tablets (chewed and swallowed), with maximum plasma concentrations of norethindrone and ethinyl estradiol occurring at 1.0 hr (range: 0.7 to 2.5 hrs) and 1.3 hr (range: 1 to 2.5 hrs) post-dose, respectively. 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-dose administrations of norethindrone acetate and ethinyl estradiol tablets (chewed and swallowed) in 35 healthy female subjects are provided in Figures 2 and 3, and Table 1.

Following multiple-dose administration of norethindrone acetate/ethinyl estradiol tablets (swallowed whole) in 17 healthy female subjects, mean maximum concentrations of norethindrone and ethinyl estradiol were increased by 95% and 27%, respectively, as compared to single-dose administration. Mean norethindrone and ethinyl estradiol exposures (AUC values) were increased by 164% and 51% respectively, as compared to single-dose administration of norethindrone acetate/ethinyl estradiol tablets.

Steady-state with respect to norethindrone was reached by Day 17 and steady-state with respect to ethinyl estradiol was reached by Day 13.

Mean SHBG concentrations were increased by 150% from baseline (57.5 nmol/L) to 144

nmol/L at steady-state.

Figure 2. Mean (± Standard Deviation) Plasma Norethindrone Concentration-Time Profile Following Single-Dose Oral Administration of Norethindrone Acetate and Ethinyl Estradiol Tablets (chewed and swallowed) to Healthy Female Volunteers under Fasting Conditions (n = 35)

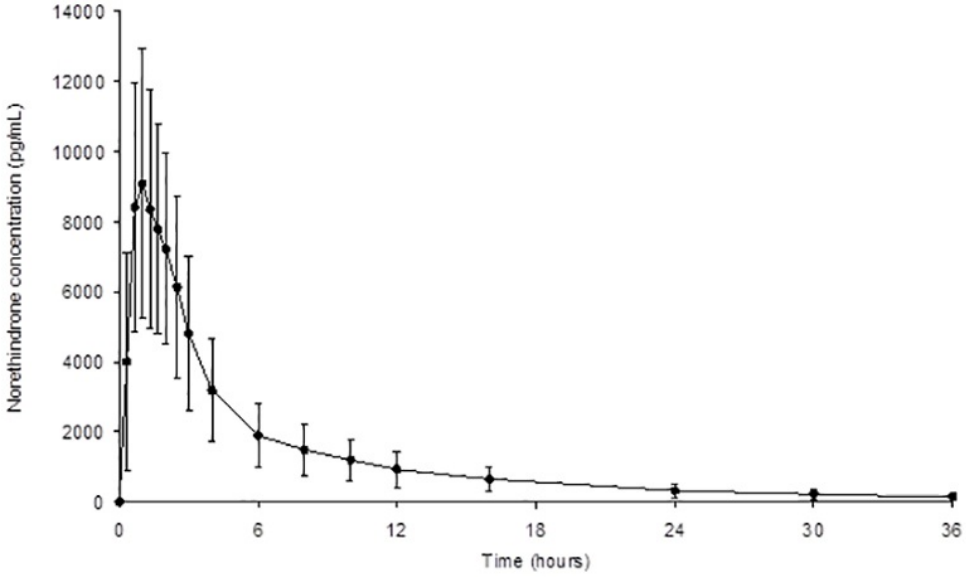


Figure 3. Mean (± Standard Deviation) Plasma Ethinyl Estradiol Concentration-Time Profile Following Single-Dose Oral Administration of Norethindrone Acetate and Ethinyl Estradiol Tablets (chewed and swallowed) to Healthy Female Volunteers under Fasting Conditions (n = 35)

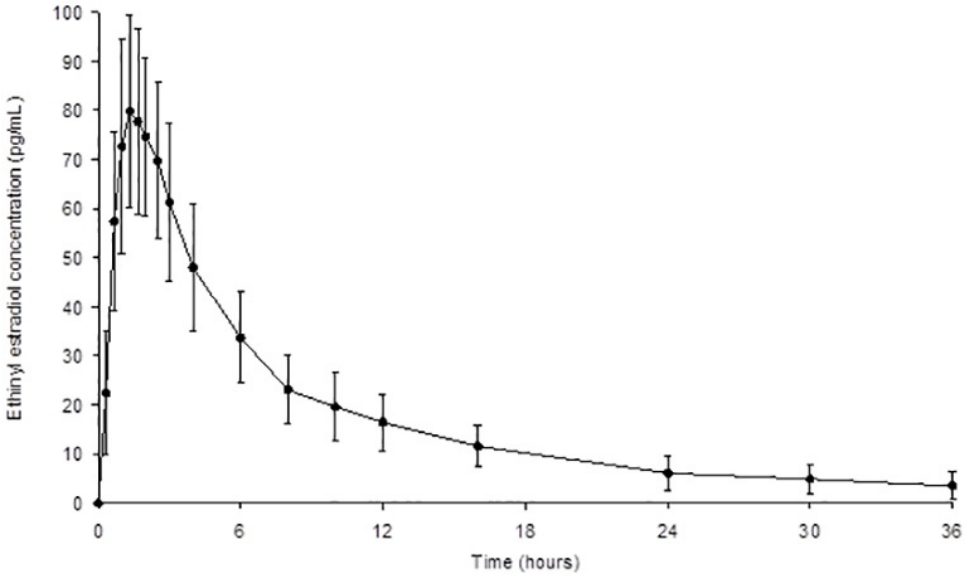


Table 1. Summary of Norethindrone (NE) and Ethinyl Estradiol (EE) Pharmacokinetics Following Single-Dose Oral Administration of Norethindrone Acetate and Ethinyl Estradiol Tablets (chewed and swallowed) to Healthy Female Volunteers Under Fasting Conditions (n = 35)

Analyte	Arithmetic Mean[a] (% CV) by Pharmacokinetic Parameter				
	C_{max} (pg/mL)	t_{max} (hr)	$AUC_{(0±tldc)}$ (pg/mL•h)	$AUC_{(0±inf)}$ (pg/mL•h)	$t_{½}$ (hr)
NE	10200 (36)	1.03 (0.67 to 2.50)	48620 (40)	49250 (40)	8.58
EE	84.7 (24)	1.33 (1.00 to 2.50)	677.5 (33)	741.6 (33)	9.68

C_{max} = Maximum plasma concentration

t_{max} = Time of C_{max}
$AUC_{(0±tldc)}$ = Area under plasma concentration versus time curve from 0 to tldc, the time of last determinable concentration
$AUC_{(0±inf)}$ = Area under the plasma concentration versus time curve from time 0 to infinity
$t_{½}$ = Terminal phase half-life
% CV = Coefficient of Variation (%)
[a] The harmonic mean (0.693/mean terminal phase rate constant) is reported for $t_{½}$, and the median (range) is reported for t_{max}

Food Effect

Finzala tablets may be administered without regard to meals.

A single-dose administration of norethindrone acetate/ethinyl estradiol tablets with food decreased the maximum concentration of norethindrone by 51% and increased the extent of absorption by 15% and decreased the maximum concentration of ethinyl estradiol by 51% 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 (greater than 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.

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). Steady-state elimination half-lives of norethindrone and ethinyl estradiol following administration of norethindrone acetate/ethinyl estradiol tablets are approximately 8 hours and 14 hours, respectively.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

[See Warnings and Precautions (5.2, 5.11)].

14 CLINICAL STUDIES

The data presented in Section 14 are from a clinical trial conducted with a 24-day regimen of norethindrone acetate 1 mg/ethinyl estradiol 20 mcg tablets. Finzala tablets are bioequivalent to these norethindrone acetate/ethinyl estradiol tablets.

In a clinical study, 743 women 18 to 45 years of age were studied to assess the efficacy of norethindrone acetate/ethinyl estradiol tablets, for up to six 28-day cycles providing a total of 3,823 treatment-cycles of exposure. The racial demographic of all enrolled women was: 70% Caucasian, 16% African-American, 10% Hispanic, 2% Asian and 2% Other. Women with body mass index (BMI) greater than 35 kg/m^2 were excluded from the study. The weight range for those women treated was 90 to 260 pounds, with a mean weight of 147 pounds. Among the women in the study, about 40% had not used hormonal contraception immediately prior to enrolling in this study.

A total of 583 women completed 6 cycles of treatment. There were a total of 5 on-treatment pregnancies in 3,565 treatment cycles during which no backup contraception was used. The Pearl Index for norethindrone acetate and ethinyl estradiol tablets was 1.82 (95% confidence interval 0.59 to 4.25).

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

Finzala® (norethindrone acetate and ethinyl estradiol tablets USP, 1 mg/20 mcg and ferrous fumarate tablets*) is available in blister cards (dispensers) containing 28 tablets:

NDC 0093-8210-62 Cartons of 3 blister cards (dispensers)

Each blister card contains 28 tablets in the following order:

- 24 white, round, flat-faced, beveled-edge, unscored (active) chewable tablets debossed with **E24** on one side and **TV** on the other side, and each containing 1 mg norethindrone acetate, USP and 20 mcg ethinyl estradiol, USP.
- 4 brown, round, flat-faced, beveled-edge, unscored (non-hormonal placebo) tablets debossed with **F75** on one side and **TV** on the other side, and each containing 75 mg ferrous fumarate, USP. The ferrous fumarate tablets do not serve any therapeutic purpose.

*Ferrous fumarate tablets are not USP for dissolution and assay.

16.2 Storage Conditions

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Keep this and all medications out of the reach of children.

17 PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Patient Information)

Counsel patients on the following information:

- Cigarette smoking increases the risk of serious cardiovascular events from COC use, and women who are over 35 years old and smoke should not use COCs.
- Finzala does not protect against HIV infection (AIDS) and other sexually transmitted infections.
- The Warnings and Precautions associated with COCs.
- Finzala is not to be used during pregnancy; if pregnancy occurs during use of Finzala, instruct the patient to stop further intake.
- Take one tablet daily by mouth at the same time every day. Instruct patients what to do in the event tablets are missed. See "*What to Do if You Miss Tablets*" section in ***FDA-approved patient labeling***.
- Use a back-up or alternative method of contraception when enzyme inducers are used with Finzala.
- COCs may reduce breast milk production. This is less likely to occur if breastfeeding is well established.
- Women who start COCs postpartum, and who have not yet had a period, should use an additional method of contraception until they have taken a white tablet for 7 consecutive days.
- Amenorrhea may occur. Rule out pregnancy in the event of amenorrhea in two or more consecutive cycles.

Manufactured By:
Teva Pharmaceuticals USA, Inc.
Parsippany, NJ 07054

Rev. C 9/2024

FDA-Approved Patient Labeling

Guide for Using Finzala® (fin-ZA-la)

(norethindrone acetate and ethinyl estradiol tablets and ferrous fumarate tablets)

WARNING TO WOMEN WHO SMOKE
Do not use Finzala 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 infections.

What is Finzala?

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

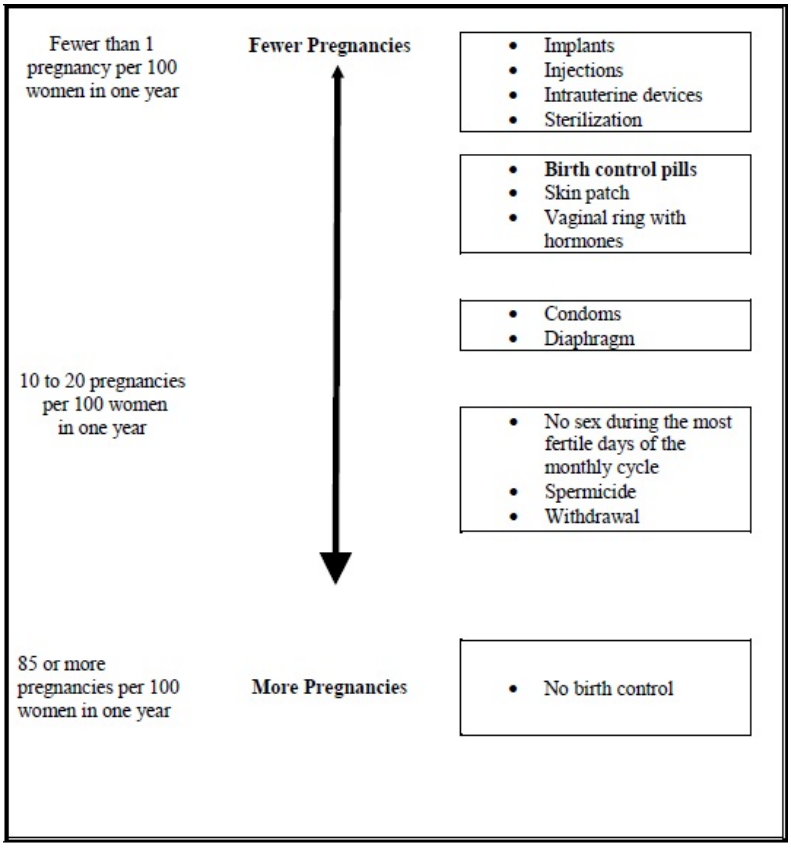
How well does Finzala work?

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 24-day regimen of norethindrone acetate 1 mg/ethinyl estradiol 20 mcg tablets lasting six months, about 1 to 4 out of 100 women may get pregnant during the first year they use Finzala.

Women with a BMI above 35 kg/m^2 were not studied in the clinical trial, so it is not known how well Finzala protects against pregnancy in such women. If you are overweight, discuss with your healthcare provider whether Finzala is the best choice for you.

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.



How do I take Finzala?

1. **Be sure to read these directions** before you start taking your tablets or anytime you are not sure what to do.

2. The tablets may be chewed and swallowed or swallowed whole. You should drink a full glass (8 ounces) of water immediately after chewing or swallowing.

3. The right way to take the tablet is to take one tablet every day at the same time in the order directed on the package. Finzala can be taken without regard to meals.
If you miss tablets you could get pregnant. This includes starting the pack late. The more tablets you miss, the more likely you are to get pregnant. See "What to Do if You

Miss Tablets" below.

4. Many women have spotting or light bleeding at unexpected times, or may feel sick to their stomach during the first 1 to 3 packs of tablets.

If you do have spotting or light bleeding or feel sick to your stomach, do not stop taking the tablets. The problem will usually go away. If it does not go away, check with your healthcare provider.

5. Missing tablets can also cause spotting or light bleeding, even when you make up these missed tablets.
On the days you take two tablets, to make up for missed tablets, you could also feel a little sick to your stomach.

6. If you have vomiting (within 3 to 4 hours after you take your tablet), you should follow the instructions for "What to Do if You Miss Tablets". If you have diarrhea or if you take certain medicines, including some antibiotics and some herbal products such as St. John's Wort, your tablets may not work as well.
Use a back-up method (such as condoms and spermicides) until you check with your healthcare provider.

7. If you have trouble remembering to take Finzala, talk to your healthcare provider about how to make tablet-taking easier or about using another method of birth control.

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

Before You Start Taking Your Finzala Tablets

1. Decide What Time of Day You Want to Take Your Tablet. It is important to take Finzala tablets in the order directed on the package at the same time every day. Finzala tablets can be taken without regard to meals.

2. Look at Your Tablet Pack – It has 28 Tablets
The Finzala pack has 24 "active" white tablets (with hormones) to be taken for 24 days, followed by 4 "reminder" brown tablets (without hormones) to be taken for the next four days.

3. Also look for:
   a) Where on the pack to start taking tablets,
   b) In what order to take the tablets (follow the arrows shown in the picture above)
   c) The week numbers as shown in the picture above.

4. Be sure you have ready at all times

a) another kind of birth control (such as a condoms and spermicide) to use as a back-up in case you miss tablets, and

b) an extra, full tablet pack.

When to Start the First Pack of Tablets

You have a choice for which day to start taking your first pack of tablets. Decide with your healthcare provider which is the best day for you. Pick a time of day which will be easy to remember.

Day 1 Start:
1. 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).
2. 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.
3. Take the first white tablet of the pack during the first 24 hours of your period.
4. You will not need to use a back-up method of birth control, since you are starting the tablet at the beginning of your period. However, if you start Finzala later than the first day of your period, you should use another method of birth control (such as a condom and spermicide) as a back-up method until you have taken 7 white tablets.

Sunday Start:
1. Take the first white tablet of the pack on the Sunday after your period starts, even if you are still bleeding. If your period begins on Sunday, start the pack that same day.
2. Use another method of birth control (such as a condom and spermicide) as a back-up method if you have sex anytime from the Sunday you start your first pack until the next Sunday (7 days). This also applies if you start Finzala after having been pregnant, and you have not had a period since your pregnancy.

When You Switch From a Different Birth Control Tablet or Capsule

When switching from another birth control pill, finish all the tablets or capsules, then Finzala should be started on the same day that a new pack of the previous birth control tablet or capsule would have been started.

When You Switch From Another Type of Birth Control Method

When switching from a transdermal patch or vaginal ring, finish the 21 days of use, wait 7 days, then Finzala should be started when the next application would have been due. When switching from an injection, Finzala should be started when the next injection would have been due. When switching from an intrauterine device or an implant, Finzala should be started on the day of removal.

What to Do During the Month
1. Take one tablet at the same time every day until the pack is empty.
   Do not skip tablets even if you are spotting or bleeding between monthly periods or feel sick to your stomach (nausea).
2. Do not skip tablets even if you do not have sex very often.
   When you finish a pack of tablets, start the next pack on the day after your last brown tablet. Do not wait any days between packs.

What to Do if You Miss Tablets

Finzala may not be as effective if you miss any white tablets, especially if you miss the first few or the last few white tablets in a pack.

If you miss 1 white tablet:
1. Take the tablet as soon as you remember. Take the next tablet at your regular time. This means you may take two tablets in one day.
2. You do not need to use a back-up birth control method if you have sex.

If you miss 2 white tablets in a row in week 1 OR week 2 of your pack:
1. Take two tablets on the day you remember and two tablets the next day.
2. Then take one tablet a day until you finish the pack.
3. **You could become pregnant** if you have sex in the 7 days after you restart your tablets. You must use another birth control method (such as a condom and spermicide) as a back-up for those 7 days.

If you miss 2 white tablets in a row in week 3 or week 4 of your pack:
1. **If you are a Day 1 Starter:**
   Throw out the rest of the tablet pack and start a new pack that same day.

   If you are a Sunday Starter:
   Keep taking one tablet every day until Sunday. On Sunday, throw out the rest of the

pack and start a new pack of tablets that same day.
2. **You could become pregnant** if you have sex in the 7 days after you restart your tablets. You must use another birth control method (such as a condom and spermicide) as a back-up for those 7 days.
3. You may not have your period this month but this is expected. **However, if you miss your period two months in a row, call your healthcare provider because you might be pregnant.**

If you miss 3 or more white tablets in a row during any week:

1. **If you are a Day 1 Starter:**
   Throw out the rest of the tablet pack and start a new pack that same day.

   If you are a Sunday Starter:
   Keep taking 1 tablet every day until Sunday. On Sunday, throw out the rest of the pack and start a new pack of tablets that same day.
2. **You could become pregnant** if you have sex on the days when you missed tablets or during the first 7 days after you restart your tablets. You must use another 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 tablets.
3. You may not have your period this month but this is expected. **However, if you miss your period two months in a row, call your healthcare provider because you might be pregnant.**

If you miss any of the 4 brown tablets in Week 4:

1. Throw away the tablets you missed.
2. Keep taking one tablet each day until the pack is empty.
3. You do not need a back-up method.
4. Start the next pack of Finzala as scheduled.

Finally, if you are still not sure what to do about the tablets you have missed:

1. Use a back-up method (such as a condom and spermicide) anytime you have sex.
2. Contact your healthcare provider and continue taking one active white tablet each day until otherwise directed.

Who should not take Finzala?

Your healthcare provider will not give you Finzala if you have:

- Ever had blood clots in your arms, legs (deep vein thrombosis), lungs (pulmonary embolism), or eyes (retinal thrombosis)
- 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 cannot control
- Diabetes with kidney, eye, nerve, or blood vessel damage
- Ever had certain kinds of severe migraine headaches with aura, numbness, weakness or changes in vision, or have any migraine headache if you are over age 35.
- Ever had breast cancer, which may be 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

Also, do not take birth control pills if you:

- Smoke and are over 35 years old
- Are or suspect you are pregnant
- Have any unexplained bleeding from the vagina

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.

Tell your healthcare provider if you have ever had any of the above conditions (your healthcare provider may recommend another method of birth control).

What else should I know about taking Finzala?

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

Do not skip any tablets, 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 every day
- 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 Finzala at least four weeks before you have 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 Finzala, may decrease the amount of milk you make. A small amount of the pill's hormones passes 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

Use a back-up or alternative 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.

Women on thyroid hormone replacement therapy may need increased doses of thyroid hormone.

If you are scheduled for any laboratory tests, tell your healthcare provider that you are taking birth control pills. Certain blood tests may be affected by birth control pills.

What are the most serious risks of taking Finzala?

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. This increased risk is highest when you first start taking birth control pills and when you restart the same or different birth control pills after not using them for a month or more.

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 (deep vein thrombosis)
- Lungs (pulmonary embolus)
- Eyes (loss of eyesight)
- Heart (heart attack)
- Brain (stroke)

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 or pressure 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 (cholesterol, triglyceride) 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 gain

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?

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 should I know about my period when taking Finzala?

Irregular vaginal bleeding or spotting may occur while you are taking Finzala. Irregular bleeding may vary from slight staining between menstrual periods to breakthrough bleeding, which is a flow much like a regular period. Irregular 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. It is important to continue taking your tablets 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.

Some women may not have a menstrual period but this should not be cause for alarm as long as you have taken the tablets according to direction.

What if I miss my scheduled period when taking Finzala?

It is not uncommon to miss your period. However, if you go two or more months in a row without a period, or you miss your period after a month where you did not take all your tablets correctly, call your healthcare provider because you may be pregnant. Also notify your healthcare provider if you have symptoms of pregnancy such as morning sickness or unusual breast tenderness. Stop taking Finzala if you are pregnant.

What if I want to become pregnant?

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

General Advice about Finzala

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

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

For more information, call Teva at 1-888-838-2872.

Manufactured By:
Teva Pharmaceuticals USA, Inc.
Parsippany, NJ 07054

Rev. B 10/2023

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 0093-8210-62

Finzala®
(norethindrone acetate and ethinyl estradiol tablets, USP and ferrous fumarate tablets*)
1 mg/20 mcg

Mint Flavor

THIS PRODUCT (LIKE ALL ORAL CONTRACEPTIVES) IS INTENDED TO PREVENT PREGNANCY. IT DOES NOT PROTECT AGAINST HIV INFECTION (AIDS) AND OTHER SEXUALLY TRANSMITTED DISEASES.

Pharmacist
The Patient Labeling enclosed in each Pouch is intended for the patient and should be dispensed with the blister card.

Provides 24 days of active therapy
*Ferrous fumarate tablets are not USP for dissolution and assay.

Rx only

Three Blister Cards, 28 Tablets Each
28 DAY REGIMEN

FINZALA

norethindrone acetate and ethinyl estradiol and ferrous fumarate kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0093-8210

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0093-8210-62	3 in 1 CARTON	08/04/2022	
1	NDC:0093-8210-28	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	1 BLISTER PACK	24
Part 2	1 BLISTER PACK	4

Part 1 of 2

NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL

norethindrone acetate and ethinyl estradiol tablet, chewable

Product Information	
Item Code (Source)	NDC:0093-3476

Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
NORETHINDRONE ACETATE (UNII: 9S44LIC7OJ) (NORETHINDRONE - UNII:T18F433X4S)	NORETHINDRONE ACETATE	1 mg
ETHINYL ESTRADIOL (UNII: 423D2T571U) (ETHINYL ESTRADIOL - UNII:423D2T571U)	ETHINYL ESTRADIOL	20 ug

Inactive Ingredients	
Ingredient Name	**Strength**
ACACIA (UNII: 5C5403N26O)	
SUCROSE (UNII: C151H8M554)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SPEARMINT OIL (UNII: C3M81465G5)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics			
Color	white	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor	SPEARMINT	**Imprint Code**	E24;TV
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0093-3476-38	24 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210087	08/04/2022	

Part 2 of 2

INERT

ferrous fumarate tablet

Product Information	
Item Code (Source)	NDC:0093-3525
Route of Administration	ORAL

Inactive Ingredients	
Ingredient Name	**Strength**
FERROUS FUMARATE (UNII: R5L488RY0Q)	75 mg
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MANNITOL (UNII: 3OWL53L36A)	
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SPEARMINT OIL (UNII: C3M81465G5)	

SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color	brown	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor	SPEARMINT	**Imprint Code**	F75;TV
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0093-3525-44	4 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210087	08/04/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210087	08/04/2022	

Labeler - Teva Pharmaceuticals USA, Inc. (001627975)

Revised: 9/2024 Teva Pharmaceuticals USA, Inc.