

Tarina[®] Fe 1/20

Norethindrone Acetate and Ethinyl Estradiol Tablets, USP and Ferrous Fumarate Tablets, 1 mg/20 mcg/75 mg

TARINA[®] Fe 1/20 IS AN AB-RATED GENERIC ORAL CONTRACEPTIVE

REFERENCE DRUG

Loestrin[®] Fe 1/20 Tablets

COMPARES TO

Gildess[®] Fe 1/20, Junel[®] Fe 1/20, Larin[®] Fe 1/20 and Microgestin[®] Fe 1/20



A progestogen-estrogen combination oral contraceptive

Single phase continuous administration regimen

- 21 white to off-white tablets of norethindrone acetate and ethinyl estradiol tablets
- 7 brown non-hormone containing tablets of ferrous fumarate to help ease administration

28-day tablet blister pack makes dosing easy and convenient

ORDERING INFORMATION

Order from your local drug distributor today

PACKING

Description	NDC	Dimensions
Carton Containing 3 Pouches	50102-128-03	156 mm x 89 mm x 61 mm

WARNINGS: Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives should be strongly advised not to smoke.

To report SUSPECTED ADVERSE REACTIONS, call 1-855-888-2467 or report via the FDA Medwatch Program at www.fda.gov/medwatch or 1-800-FDA-1088.

Please see reverse side for Important Safety Information and the accompanying full Prescribing Information.

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Ferrous Fumarate Tablets, 1 mg/20 mcg/75 mg

Important Safety Information

Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

INDICATIONS AND USAGE

Tarina[®] Fe 1/20 is indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception.

CONTRAINDICATIONS

Oral contraceptives should not be used in women who currently have the following conditions:

- Thrombophlebitis or thromboembolic disorders
- A past history of deep vein thrombophlebitis or thromboembolic disorders
- Cerebral vascular or coronary artery disease
- Known or suspected carcinoma of the breast
- Carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia
- Undiagnosed abnormal genital bleeding
- Cholestatic jaundice of pregnancy or jaundice with prior pill use
- Hepatic adenomas or carcinomas
- Known or suspected pregnancy

WARNINGS

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RISKS

The use of oral contraceptives is associated with increased risks of several serious conditions including myocardial infarction, thromboembolism, stroke, hepatic neoplasia and gallbladder disease, although the risk of serious morbidity or mortality is very small in healthy women without underlying risk factors. The risk of morbidity and mortality increases significantly in the presence of other underlying risk factors such as hypertension, hyperlipidemias, obesity and diabetes.

SIDE EFFECTS

Most side effects of the pill are not serious. The most common side effects are nausea, vomiting, bleeding between menstrual periods, weight gain, breast tenderness, and difficulty wearing contact lenses. These side effects, especially nausea, vomiting, and breakthrough bleeding may subside within the first three months of use.

DOSAGE AND ADMINISTRATION

To achieve maximum contraceptive effectiveness, Tarina Fe 1/20 should be taken exactly as directed and at intervals not exceeding 24 hours.

Please see accompanying full Prescribing Information or online at afaxys.com.