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# Femcon Fe (Norethindrone and Ethinyl Estradiol Tablets)

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section): **WARNINGS** An increased risk of the following serious adverse reactions has been associated with the use of oral contraceptives (see

- Thrombophlebitis
- Arterial thromboembolism
- Pulmonary embolism
- Myocardial infarction
- Cerebral hemorrhage
- Cerebral thrombosis
- Hypertension
- Gallbladder disease
- Hepatic adenomas or benign liver tumors

There is evidence of an association between the following conditions and the use of oral contraceptives:

- Mesenteric thrombosis
- Retinal thrombosis

The following adverse reactions have been reported in patients receiving oral contraceptives and are believed to be drug related:

- Nausea
- Vomiting
- Gastrointestinal symptoms (such as abdominal pain, cramps and bloating)
- Breakthrough bleeding
- Spotting
- Change in menstrual flow
- Amenorrhea
- Temporary infertility after discontinuation of treatment
- Edema/fluid retention
- Melasma/chloasma which may persist
- Breast changes: tenderness, pain, enlargement, and secretion
- Change in weight or appetite (increase or decrease)
- Change in cervical ectropion and secretion
- Possible diminution in lactation when given immediately postpartum
- Cholestatic jaundice
- Migraine headache
- Rash (allergic)
- Mood changes, including depression
- Vaginitis, including candidiasis
- Change in corneal curvature (steepening)
- Intolerance to contact lenses
- Decrease in serum folate levels
- Exacerbation of systemic lupus erythematosus
- Exacerbation of porphyria
- Exacerbation of chorea
- Aggravation of varicose veins
- Anaphylactic/anaphylactoid reactions, including urticaria, angioedema, and severe reactions with respiratory and circulatory symptoms

The following adverse reactions have been reported in users of oral contraceptives, and a causal association has been neither confirmed nor refuted:

- Premenstrual syndrome
- Cataracts
- Optic neuritis, which may lead to partial or complete loss of vision
- Cystitis-like syndrome

- Headache •
- Nervousness •
- Dizziness •
- Hirsutism •
- Loss of scalp hair •
- Erythema multiforme •
- Erythema nodosum •
- Hemorrhagic eruption •
- Impaired renal function •
- Hemolytic uremic syndrome •
- Budd-Chiari syndrome •
- Acne •
- Changes in libido •
- Colitis •
- Pancreatitis •
- Dysmenorrhea •