Although available evidence is suggestive of an association, such a relationship has been neither confirmed nor refuted for the following serious adverse reactions:

Neuro-ocular lesions, e.g., retinal thrombosis and optic neuritis

The following adverse reactions are known to occur in patients receiving oral contraceptives:

Nausea
Vomiting
Gastrointestinal symptoms (such as abdominal cramps and bloating)
Breakthrough bleeding
Spotting
Change in menstrual flow
Amenorrhea during and after treatment
Edema
Chloasma or melasma
Breast changes: tenderness, enlargement and secretion
Change in weight (increase or decrease)
Changes in cervical erosion and cervical secretions
Suppression of lactation when given immediately postpartum
Cholestatic Jaundice
Migraine
Rash (Allergic)
Rise in blood pressure in susceptible individuals
Mental depression

Although the following adverse reactions have been reported in users of oral contraceptives, an association has been neither confirmed nor refuted:

Anovulation post treatment
Premenstrual-like syndrome
Changes in libido
Changes in appetite
Cystitis-like syndrome
Headache
Nervousness
Dizziness
Fatigue
Backache
Hirsutism
Loss of scalp hair
Erythema multiforme
Erythema nodosum
Hemorrhagic eruption
Itching

The following laboratory results may be altered by the use of oral contraceptives:

Hepatic function: Increased sulfobromophthalein retention and other tests
Coagulation tests: Increase in prothrombin, Factors VII, VIII, IX, and X
Thyroid function: Increase in PBI, and butanol extractable protein bound iodine and decrease in T^3 uptake values
Metayrapone test
Pregnanediol determination

DOSAGE AND ADMINISTRATION

This section includes routine administration and specific instructions on handling problems such as breakthrough bleeding, amenorrhea, etc.

CLINICAL STUDIES (AN OPTIONAL SECTION)

If any clinical data are included, the following paragraph must be used: Different pregnancy and adverse reaction rates have been reported with the use of each oral contraceptive. Inasmuch as these rates are usually derived from separate studies conducted by different investigators in several population groups, they cannot be compared with precision. Furthermore, pregnancy and adverse reaction rates tend to be lower as clinical experience is expanded, possibly due to retention in the clinical study of those patients who accept the treatment regimen and did not discontinue due to adverse reactions or pregnancy. In clinical trials with * * * patients completed * * * cycles, and a total of * * * pregnancies was reported. This represents a pregnancy rate of * * * per 100 woman years. Please see the SPECIAL NOTE in this labeling.