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Cyred™
(Desogestrel and Ethinyl Estradiol Tablets USP, 0.15 mg/0.03 mg)

CYRED™ IS AN AB-RATED GENERIC ORAL CONTRACEPTIVE

REFERENCE DRUG
Ortho-Cept®

COMPARES TO
Apri®, Desogen®, Emoquette®, Reclipsen®, Solia®, Enskyce® and Isibloom™

A progestogen-estrogen combination oral contraceptive

Bi-phasic continuous administration regimen:

- 21 white active tablets containing desogestrel and ethinyl estradiol
- 7 inactive "reminder" tablets

Simple 28-blister pack supports a choice of dosing schedules

- Start on the first day of a woman's period for efficacy from day one
- Start on the first Sunday following the start of a woman's period for the convenience of aligning with other weekly cycles
  - First dose requires seven days to achieve full efficacy

ORDERING INFORMATION

Order from your local drug distributor today

PACKING

Description	NDC	Dimensions
Carton Containing 3 Pouches	50102-154-03	156 mm x 89 mm x 61 mm

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.

Cyred™

(Desogestrel and Ethinyl Estradiol Tablets USP, 0.15 mg/0.03 mg)

Important Safety Information

Indication and Usage of Cyred™
Cyred is indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception.

SELECTED SAFETY INFORMATION about Cyred

WARNINGS: CIGARETTE SMOKING AND SERIOUS CARDIOVASCLAR EVENTS
Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptive use. This risk increases with age, particularly in women over 35 years of age, and with the number of cigarettes smoked. For this reason, combination oral contraceptives, including Cyred, should not be used by women over 35 years of age and smoke.

BRIEF SUMMARY: Consult the Package Insert for Complete Prescribing Information
CONTRAINDICATIONS
Do not prescribe combined oral contraceptives (COCs) to women who currently have the following conditions:

- A high risk of arterial or venous thrombotic disease including women who are known to smoke if over age 35, have a current or past history of deep vein thrombosis, pulmonary embolism, thrombophlebitis, thrombophilic conditions or thromboembolic disorders, have cerebrovascular or coronary artery disease(current or history), have valvular heart disease with complications, have persistent blood pressure values of greater than or equal to 160 mm Hg systolic or greater than or equal to 100 mm Hg diastolic, have headache with focal neurologic symptoms, or have diabetes with vascular involvement
- Major surgery with prolonged immobilization
- Known or suspected carcinoma of breast or personal history of breast cancer; carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia
- Undiagnosed abnormal genital bleeding
- Acute or chronic hepatocellular disease with abnormal liver function, hepatic adenomas or carcinoma
- Cholestatic jaundice of pregnancy or jaundice with prior contraceptive pill use
- Known or suspected pregnancy
- Hypersensitivity to any of the components of the oral contraceptive pills

WARNINGS AND PRECAUTIONS

- **Thrombotic and other vascular events -** Stop combined oral contraceptives if an arterial or venous thrombotic event occurs, 4 weeks before and 2 weeks after major surgeries or surgeries known to have an elevated risk of thromboembolism, or if there is an unexplained loss or change of vision (Evaluate for retinal thrombosis immediately.). Combined oral contraceptives should be used with caution in women with cardiovascular risk factors.
- **Carcinoma of the breast and cervix -** Women with current or past history of breast cancer should not use COCs.
- **Liver Disease -** Discontinue COCs if jaundice develops. Hepatic adenomas and very rare hepatocellular carcinoma (> 8 years use) are associated with COC use.
- **High Blood pressure -** Women with well-controlled hypertension should be monitored closely. Women with uncontrolled hypertension should not use COCs.
- **Other warnings and precautions** include gall bladder disease, carbohydrate and lipid metabolic effects, headache, bleeding irregularities including amenorrhea, COC use before and during pregnancy, depression, and interference with laboratory tests.

ADVERSE REACTIONS
The most serious reactions are discussed elsewhere in the labeling and include serious cardiovascular events and smoking, vascular events and liver disease. Commonly reported adverse reactions include irregular uterine bleeding, nausea, breast tenderness and headache.

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

To report a Suspected Adverse Reaction to Cyred, please contact the Afaxys Health and Safety team at 1-855-888-2467.

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