

## Oral Contraceptives

### **Aubra**<sup>®</sup> (Levonorgestrel and Ethinyl Estradiol Tablets, USP 0.1/0.02 mg)

**REFERENCE DRUG**

Lutera<sup>®</sup>

**COMPARES TO**

Aviana<sup>®</sup>, Lessina<sup>®</sup>, Levlite<sup>®</sup>, Orsythia<sup>®</sup>, Sronyx<sup>®</sup>, Alesse<sup>®</sup>, and Falmina<sup>®</sup>

NDC# 50102-0120-48



### **Chateal**<sup>®</sup> (Levonorgestrel and Ethinyl Estradiol Tablets, USP 0.15/0.03 mg)

**REFERENCE DRUG**

Nordette<sup>®</sup>

**COMPARES TO**

Levora<sup>®</sup>, Portia<sup>®</sup>, Altavera<sup>®</sup>, Marlissa<sup>®</sup>, and Kurvelo<sup>®</sup>

NDC# 50102-0130-48



### **Cyred**<sup>™</sup> (Desogestrel and Ethinyl Estradiol Tablets USP, 0.15 mg/0.03 mg)

**REFERENCE DRUG**

Ortho-Cept<sup>®</sup>

**COMPARES TO**

Apri<sup>®</sup>, Desogen<sup>®</sup>, Emoquette<sup>™</sup>, Reclipsen<sup>™</sup>, Solia<sup>™</sup>, and Enskyce<sup>™</sup>

NDC# 50102-154-03



### **Lyza**<sup>®</sup> (Norethindrone Tablets, USP 0.35 mg)

**REFERENCE DRUG**

Ortho Micronor<sup>®</sup>

**COMPARES TO**

Nor-QD<sup>®</sup>, Nora-BE<sup>®</sup>, Errin<sup>®</sup>, Heather<sup>®</sup>, Jolivette<sup>®</sup>, Camila<sup>®</sup>, Jencycla<sup>®</sup>, and norethindrone

NDC# 50102-0100-48



### **Tarina**<sup>®</sup> FE 1/20 (Norethindrone Acetate and Ethinyl Estradiol Tablets, USP and Ferrous Fumarate Tablets, 1mg/20mcg/75mg)

**REFERENCE DRUG**

Loestrin<sup>®</sup> FE 1/20 Tablets

**COMPARES TO**

Gildess<sup>®</sup> FE 1/20, Junel<sup>®</sup> FE 1/20, Larin<sup>®</sup> FE 1/20, Microgestin<sup>®</sup> FE 1/20

NDC# 50102-128-03



## Emergency Contraceptives

### **ella**<sup>®</sup> (ulipristal acetate 30 mg)

ella is the only 30 mg ulipristal acetate tablet currently available.

NDC# 50102-911-01

GPI# 25-40-00-70-10-03-20



### **EContra**<sup>®</sup> EZ (Levonorgestrel Tablet, 1.5 mg)

**REFERENCE DRUG**

Plan B One-Step<sup>®</sup>

**COMPARES TO**

Take Action<sup>™</sup>, Next Choice One Dose<sup>™</sup>, My Way<sup>®</sup>, AfterPill<sup>™</sup>, Fallback Solo<sup>™</sup>, Opicon<sup>™</sup> One-Step

NDC# 50102-111-12

GPI# 25400040000340



Please see accompanying full Prescribing Information including the Boxed Warning.

**WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR 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 Chateal, Aubra, Tarina Fe 1/20 and Cyred, should not be used by women who are over 35 years of age and smoke.

#### IMPORTANT SAFETY INFORMATION FOR ORAL CONTRACEPTIVES

**Important Safety Information for the Combined Oral Contraceptives (COCs) Chateal**<sup>®</sup> (levonorgestrel and ethinyl estradiol tablets, USP 0.15/0.03 mg), **Aubra**<sup>®</sup> (levonorgestrel and ethinyl estradiol tablets, USP 0.1/0.02 mg), **Tarina**<sup>®</sup> Fe 1/20 (norethindrone acetate and ethinyl estradiol tablets, USP and ferrous fumarate tablets, (1.0/0.02 mg and 75 mg) and **Cyred**<sup>™</sup> (desogestrel and ethinyl estradiol tablets USP 0.15mg/0.03mg).<sup>1</sup>

#### Indication and Usage of Chateal, Aubra, Tarina Fe 1/20 and Cyred

Chateal, Aubra, Tarina Fe 1/20 and Cyred are indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception.

#### SELECTED SAFETY INFORMATION about Chateal, Aubra, Tarina Fe 1/20 and Cyred, including Boxed Warning

##### WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS

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**Combined Oral Contraceptives BRIEF SUMMARY: Consult the Package Insert for Complete Prescribing Information for each product**

#### CONTRAINDICATIONS

Do not prescribe combined oral contraceptives 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, endometrium or estrogen sensitive neoplasias** – Women with current or past history of these diseases 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 in detail in the full product 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 COCs do not protect against HIV infection (AIDS) and other sexually transmitted diseases.**

#### References:

1. Chateal<sup>®</sup>, Aubra<sup>®</sup>, Tarina<sup>®</sup> Fe 1/20 and Cyred<sup>™</sup> prescribing information. Charleston, SC: Afaxys Inc. 2015
2. Lyza<sup>®</sup> prescribing information. Charleston, SC: Afaxys, Inc. 2015
3. ella<sup>®</sup> prescribing information. Charleston, SC: Afaxys, Inc. 2015
4. EContra<sup>®</sup> EZ product information. Charleston, SC: Afaxys, Inc. 2015

#### Important Safety Information for Lyza<sup>®</sup> (Norethindrone 0.35mg tablet USP)<sup>2</sup>

**CONTRAINDICATIONS** include known or suspected pregnancy, known or suspected carcinoma of the breast, undiagnosed abnormal genital bleeding, benign or malignant liver tumors or active liver disease and hypersensitivity to any components of the pills.

**WARNINGS** include ectopic pregnancy considerations, delayed follicular atresia/ovarian cysts, irregular genital bleeding, carcinoma of the breast and reproductive organs, and hepatic neoplasias.

**PRECAUTIONS** include carbohydrate and lipid metabolism, drug interactions, interactions with laboratory tests, pregnancy, nursing mothers, pediatric use, fertility following discontinuation and headache.

**ADVERSE REACTIONS** reported with progestin only pills include menstrual irregularities, headache, breast tenderness, nausea and dizziness. Androgenic side effects such as acne, hirsutism and weight gain occur rarely.

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

#### IMPORTANT SAFETY INFORMATION FOR EMERGENCY CONTRACEPTIVES

##### ella<sup>®</sup> Important Safety Information<sup>3</sup>

The most common side effects of ella (ulipristal acetate) tablets include headache (18%), abdominal pain (12%), nausea (12%), dysmenorrhea (9%), fatigue (6%), and dizziness (5%). ella is contraindicated in women with a known or suspected pregnancy, and should not replace a regular method of contraception. ella is not indicated for termination of an existing pregnancy. Women who become pregnant or complain of lower abdominal pain after taking ella should be evaluated for ectopic pregnancy. ella may alter the next expected menses. If menses is delayed beyond 1 week, pregnancy should be ruled out. ella is not recommended for use in breastfeeding women. A rapid return of fertility is likely following treatment with ella, therefore, a reliable barrier method of contraception should be used with subsequent acts of intercourse in that same menstrual cycle. Because ella and the progestin component of hormonal contraceptives both bind to the progesterone receptor, using them together could reduce their contraceptive effectiveness. After using ella, if a woman wishes to use hormonal contraception, she should do so no sooner than 5 days after intake of ella. Repeated use of ella within the same menstrual cycle is not recommended. Drugs or herbal products that induce CYP3A4 decrease the effectiveness of ella. ella does not protect against STI/HIV.

##### EContra<sup>®</sup> EZ Product Information<sup>4</sup>

###### Usage

EContra EZ (Levonorgestrel 1.5 mg tablet) is a progestin-only emergency contraceptive indicated for use in women 17 years of age and older to reduce chance of pregnancy after unprotected sex (if contraceptive failed or birth control not used). EContra EZ is not intended to be used in place of routine birth control.

###### Who Should Not Use EContra EZ

Women who are known to be pregnant as it will not work. However, EContra EZ will not harm an existing pregnancy.

Women known to be allergic to Levonorgestrel.

###### Side Effects May Include:

- Menstrual changes. After EContra EZ women may experience heavier or lighter bleeding. If the next period is more than a week late, consider pregnancy.
- Abdominal pain. Ectopic pregnancy should be considered in cases of severe abdominal pain.
- Nausea or vomiting. If women vomit within 2 hours of taking the medication, consider recommending a second dose.
- Tiredness
- Headaches
- Dizziness
- Breast Pain