Lyza™
(Norethindrone Tablets, USP 0.35 mg)

PRODUCT INFORMATION SHEET

GENERIC NAME
Norethindrone Tablets, USP 0.35 mg

REFERENCE DRUG
Ortho Micronor®

COMPARES TO
Nor-QD®, Nora-BE®, Erinn®, Heather®, Jolivette®, Camila®, Jencycla®, norethindrone

DRUG INFORMATION CLASSIFICATION NUMBER
68:12.00, oral

ANDA NUMBER
200980

DATE OF FDA APPROVAL
6/13/13

INGREDIENTS
Each tablet contains 0.35 mg norethindrone. Inactive ingredients include corn starch, D&C yellow no. 10, ethyl cellulose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, povidone, sodium starch glycolate, and talc.

STORAGE INFORMATION
Store at 20°–25° C (68°–77° F) [See USP Controlled Room Temperature].

TABLET DESCRIPTION
Yellow, round, flat-faced, beveled edge, and debossed with 220 on one side.

ADDITIONAL INFORMATION
To report SUSPECTED ADVERSE REACTIONS contact the Afaxys Health and Safety team at 1-855-888-2467 or report to the FDA Medwatch Program at 1-800-FDA-1088 or online at www.fda.gov/medwatch.
For product quality issues or medical information contact Afaxys at 1-855-888-2467.

IMPORTANT SAFETY INFORMATION
Please see reverse side for Lyza Important Safety Information.

PLEASE SEE ACCOMPANYING FULL PRESCRIBING INFORMATION INCLUDING WARNINGS, CONTRAINDICATIONS, DRUG INTERACTIONS, PRECAUTIONS, AND ADVERSE REACTIONS TO Lyza.

Ordering and Contact Information:
To open an account or order directly from Seacoast Medical:
Phone: 1-877-410-0811 Online: www.seacoastmedical.com/afaxys
For more information about Afaxys Pharmaceuticals, please visit www.afaxys.com/pharma or call 1-855-4AFAXYS (1-855-423-2997)

PACKAGING

<table>
<thead>
<tr>
<th>Description</th>
<th>NDC</th>
<th>Dimensions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monocarton containing 28-tablet Blister Pack</td>
<td>50102-100-01</td>
<td>105 mm x 18 mm x 74 mm</td>
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<tr>
<td>Clinic Pack containing 48 Monocartons</td>
<td>50102-100-48</td>
<td>250 mm x 302 mm x 109 mm</td>
</tr>
<tr>
<td>Shipper containing 3 Clinic Packs</td>
<td>50102-100-90</td>
<td>325 mm x 270 mm x 360 mm</td>
</tr>
</tbody>
</table>
Lyza™ IMPORTANT SAFETY INFORMATION

Lyza
Norethindrone Tablets, USP 0.35 mg

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

INDICATIONS
Progestin-only oral contraceptives are indicated for the prevention of pregnancy.

Efficacy
If used perfectly, the first-year failure rate for progestin-only oral contraceptives is 0.5%. However, the typical failure rate is estimated to be closer to 5%, due to late or omitted pills.¹

Lyza Tablets have not been studied for and are not indicated for use in emergency contraception.

CONTRAINDICATIONS
Progestin-only oral contraceptives (POPs) should not be used by women who currently have the following conditions:
• Known or suspected pregnancy
• Known or suspected carcinoma of the breast
• Undiagnosed abnormal genital bleeding
• Hypersensitivity to any component of this product
• Benign or malignant liver tumors
• Acute liver disease

WARNINGS
Cigarette smoking increases the risk of serious cardiovascular disease. Women who use oral contraceptives should be strongly advised not to smoke.

1. ECETIC PREGNANCY
Healthcare professionals should be alert to the possibility of an ectopic pregnancy in women who become pregnant or complain of lower abdominal pain while on progestin-only oral contraceptives.

2. DELAYED FOLLICULAR ATRESIA/OVARIAN CYSTS
If follicular development occurs, atresia of the follicle is sometimes delayed and the follicle may continue to grow beyond the size it would attain in a normal cycle. Generally these enlarged follicles disappear spontaneously. Often they are asymptomatic; in some cases they are associated with mild abdominal pain. Rarely they may twist or rupture, requiring surgical intervention.

3. IRREGULAR GENITAL BLEEDING
Irregular menstrual patterns are common among women using progestin-only oral contraceptives. If genital bleeding is suggestive of infection, malignancy, or other abnormal conditions, such nonpharmacologic causes should be ruled out. If prolonged amenorrhea occurs, the possibility of pregnancy should be evaluated.

4. CARCINOMA OF THE BREAST AND REPRODUCTIVE ORGANS
Some epidemiological studies of oral contraceptive users have reported an increased relative risk of developing breast cancer, particularly at a younger age and apparently related to duration of use. These studies have predominantly involved combined oral contraceptives, and there is insufficient data to determine whether the use of POPs similarly increases the risk.

Women with breast cancer should not use oral contraceptives because the role of female hormones in breast cancer has not been fully determined.

Some studies suggest that oral contraceptive use has been associated with an increase in the risk of cervical intraepithelial neoplasia in some populations of women. However, there continues to be controversy about the extent to which such findings may be due to differences in sexual behavior and other factors. There is insufficient data to determine whether the use of POPs increases the risk of developing cervical intraepithelial neoplasia.

5. HEPATIC NEOPLASIA
Benign hepatic adenomas are associated with combined oral contraceptive use, although the incidence of benign tumors is rare in the United States. Rupture of benign, hepatic adenomas may cause death through intraabdominal hemorrhage.

Studies have shown an increased risk of developing hepatocellular carcinoma in combined oral contraceptive users. However, these cancers are rare in the U.S. There is insufficient data to determine whether POPs increase the risk of developing hepatic neoplasia.

INFORMATION FOR THE PATIENT
Counseling Issues
The following points should be discussed with prospective users before prescribing progestin-only oral contraceptives:
• The necessity of taking pills at the same time every day, including throughout all bleeding episodes.
• The need to use a backup method such as condoms and spermicides for the next 48 hours whenever a progestin-only oral contraceptive is taken 3 or more hours late.
• The potential side effects of progestin-only oral contraceptives, particularly menstrual irregularities.
• The need to inform the healthcare professional of prolonged episodes of bleeding, amenorrhea, or severe abdominal pain.
• The importance of using a barrier method in addition to progestin-only oral contraceptives if a woman is at risk of contracting or transmitting STDs/HIV.

DOSEAGE AND ADMINISTRATION
To achieve maximum contraceptive effectiveness, Lyza must be taken exactly as directed. One tablet is taken every day, at the same time. Administration is continuous, with no interruption between pill packs.