# **AFAXYS PHARMA**

# BIRTH CONTROL REFERENCE CHART



#### Ordering and Contact Information:

Phone: PA 1-800-262-7770 KY 1-866-228-9758

Website: rsnortheast.com

## **ORAL CONTRACEPTIVES**

### Aubra EQ®

(levonorgestrel and ethinyl estradiol tablets, USP) 0.1 mg/0.02 mg

#### **COMPARES TO:**

Aubra®, Aviane®, Falmina™, Lutera®, and Orsythia®



#### Order Number: 0220230

## Chateal EQ®

(levonorgestrel and ethinyl estradiol tablets, USP) 0.15 mg/0.03 mg

#### **COMPARES TO:**

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



#### Order Number: 023023

# **Cyred EQ®**

(desogestrel and ethinyl estradiol tablets, USP) 0.15 mg/0.03 mg

#### **COMPARES TO:**

Apri $^{\otimes}$ , Cyred $^{\otimes}$ , Emoquette $^{\otimes}$ , Enskyce $^{\text{TM}}$ , Isibloom $^{\text{TM}}$ , and Reclipsen $^{\text{TM}}$ 



Order Number: 025423

## **Jasmiel®**

(drospirenone and ethinyl estradiol tablets, USP) 3 mg/0.02 mg

#### **COMPARES TO:**

Gianvi $^{\otimes}$ , Loryna $^{\text{TM}}$ , Nikki $^{\text{TM}}$ , and Yaz $^{\otimes}$ 



Order Number: 024023

# Lyleq®

(norethindrone tablets, USP) 0.35 mg

#### **COMPARES TO:**

Camila®, Heather®, Incassia®, Nor-QD®, and Tulana



#### Order Number: 030013

## Tarina® 24 Fe

(norethindrone acetate and ethinyl estradiol tablets, USP and ferrous fumarate tablets) 1 mg/20 mcg and 75 mg

#### **COMPARES TO:**

Blisovi™ 24 Fe, Junel® Fe 24, and Larin™ 24 Fe



Order Number: 022423

## Tarina Fe 1/20 EQ®

(norethindrone acetate and ethinyl estradiol tablets, USP and ferrous fumarate tablets) 1 mg/20 mcg and 75 mg

#### **COMPARES TO:**

Gildess® Fe 1/20, Junel® Fe 1/20, Larin™ Fe 1/20, Microgestin® Fe 1/20, and Tarina® Fe 1/20



Order Number: 022823

# Tri-VyLibra®

(norgestimate and ethinyl estradiol tablets, USP) 0.180 mg/0.035 mg, 0.215 mg/0.035 mg, and 0.250 mg/0.035 mg

#### **COMPARES TO:**

Ortho Tri-Cyclen®, Tri-Estarylla™, Tri-Linyah®, Tri-Mili™, Tri-Previfem®, Tri-Sprintec®, and TriNessa®



Order Number: 023313

# Tri-VyLibra® Lo

(norgestimate and ethinyl estradiol tablets, USP) 0.180 mg/ 0.025 mg, 0.215 mg/0.025 mg, and 0.250 mg/0.025 mg

#### **COMPARES TO:**

Ortho Tri-Cyclen® Lo, Tri-Lo-Estarylla  $^{T\!M}$  , Tri-Lo-Marzia  $^{T\!M}$  , and Tri-Lo-Sprintec®



Order Number: 0231130

# **VyLibra**®

(norgestimate and ethinyl estradiol tablets, USP) 0.250 mg/0.035 mg

#### **COMPARES TO:**

Estarylla™, Mili®, Mono-Linyah™, MonoNessa®, Ortho-Cyclen®, Previfem®, and Sprintec®



Order Number: 023513

Please see Important Safety Information on the following pages, and accompanying full Prescribing Information, including Boxed Warnings.

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

Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptive (COC) 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 Aubra EQ, Chateal EQ, Cyred EQ, Tarina Fe 1/20 EQ, Tri-VyLibra, Tri-VyLibra Lo, and VyLibra should not be used by women who are over 35 years of age and smoke.

#### JASMIEL AND TARINA 24 FE WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS

Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptive (COC) use. This risk increases with age, particularly in women over 35 years of age, and with the number of cigarettes smoked. For this reason, COCs are contraindicated in women who are over 35 years of age and smoke.

#### LYLEQ WARNING

Cigarette smoking greatly increases the possibility of suffering heart attacks and strokes. Women who use oral contraceptives are strongly advised not to smoke.

# **AFAXYS PHARMA**

# BIRTH CONTROL REFERENCE CHART



**Ordering and Contact Information:** 

Phone: PA 1-800-262-7770 KY 1-866-228-9758

Website: rsnortheast.com

## INJECTABLE CONTRACEPTIVE

# medroxyPROGESTERone Acetate Injectable Suspension, USP

150 mg/mL for intramuscular use

MedroxyPROGESTERone acetate injectable suspension is a progestin indicated for use by females of reproductive potential to prevent pregnancy. <u>Limitations of Use</u>: The use of medroxyPROGESTERone acetate injectable suspension is not recommended as a long-term (i.e., longer than 2 years) birth control method unless other options are considered inadequate.<sup>1</sup>

# medroxyPRGESSTERRone Acetate Injectable Suspension, USP 150 mg/mL No mily 1 mt. Fertilise Syntogs For instrumentation are easily Instrumentation and Instrumentation are easily Instrumentation and Instrumentation and Instrumentation are easily Instrumentation and Instrumentat

This is an injectable contraceptive in a ready-to-use, prefilled syringe.

#### **COMPARES TO:**

Depo-Provera®

Order Number: 0591400

#### WARNING: LOSS OF BONE MINERAL DENSITY

- Women who use medroxyPROGESTERONEone acetate injectable suspension may lose significant bone mineral density. Bone loss is greater with increasing duration of use and may not be completely reversible.
- It is unknown if use of medroxyPROGESTERONEone acetate injectable suspension during adolescence or early adulthood, a critical period of bone accretion, will reduce peak bone mass and increase the risk for osteoporotic fracture in later life.
- MedroxyPROGESTERONEone acetate injectable suspension should not be used as a long-term birth control method (i.e., longer than 2 years) unless other birth control
  methods are considered inadequate.

## **EMERGENCY CONTRACEPTIVE**

# **EContra One-Step®**

(levonorgestrel) tablet, 1.5 mg — OTC

EContra One-Step  $^{\otimes}$  is an over-the-counter emergency contraceptive that is comparable to Plan B One-Step  $^{\otimes}$  .

# OTHER 1.5 MG LEVONORGESTREL EMERGENCY CONTRACEPTIVE PRODUCTS INCLUDE:

Aftera®, AfterPill®, EContra® EZ, My Way®, Opcicon™ One-Step, and Take Action®



Order Number: 021113

IMPORTANT SAFETY INFORMATION for Aubra EQ® (levonorgestrel and ethinyl estradiol tablets, USP 0.1 mg/0.02 mg), Chateal EQ® (levonorgestrel and ethinyl estradiol tablets, USP 0.15 mg/0.03 mg), Cyred EQ® (desogestrel and ethinyl estradiol tablets, USP 0.15 mg/0.03 mg), Tarina Fe 1/20 EQ® (norethindrone acetate and ethinyl estradiol tablets, USP and ferrous fumarate tablets, 1.0 mg/20 mcg and 75 mg), Tri-VyLibra® (norgestimate and ethinyl estradiol tablets, USP 0.180 mg/0.035 mg, 0.215 mg/ 0.035 mg, and 0.250 mg/0.035 mg) and Tri-VyLibra® Lo (norgestimate and ethinyl estradiol tablets, USP 0.250 mg/0.025 mg, 0.250 mg/0.035 mg)²8

#### **INDICATIONS**

Aubra EQ, Chateal EQ, Cyred EQ, Tarina Fe 1/20 EQ, Tri-VyLibra Lo, and VyLibra are indicated for use by females of reproductive potential to prevent pregnancy.

**Tri-VyLibra** is indicated for use by females of reproductive potential to prevent pregnancy. Tri-VyLibra is indicated for the treatment of moderate acne vulgaris in females at least 15 years of age, who have no known contraindications to oral contraceptive therapy and have achieved menarche. Tri-VyLibra should be used for the treatment of acne only if the patient desires an oral contraceptive for birth control.

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

Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptive (COC) 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 Aubra EQ, Chateal EQ, Cyred EQ, Tarina Fe 1/20 EQ, Tri-VyLibra, Tri-VyLibra Lo, and VyLibra should not be used by women who are over 35 years of age and smoke.

Consult the Package Insert or click below for Complete Prescribing Information:

Aubra EQ Tri-VyLibra
Chateal EQ Tri-VyLibra Lo
Cyred EQ VyLibra

Tarina Fe 1/20 EQ

#### CONTRAINDICATIONS

Do not prescribe COCs to women who are known to have the following conditions:

- A high risk of arterial or venous thrombotic diseases. Examples include women who are known to:
- o Smoke, if over age 35
- O Have deep vein thrombosis or pulmonary embolism, now or in the past
- O Have inherited or acquired hypercoagulopathies
- O Have cerebrovascular disease
- O Have coronary artery disease
- Have thrombogenic valvular or thrombogenic rhythm diseases of the heart (for example, subacute bacterial endocarditis with valvular disease, or atrial fibrillation)
- O Have uncontrolled hypertension
- O Have diabetes mellitus with vascular disease
- O Have headaches with focal neurological symptoms or migraine headaches with aura or women over age 35 with any migraine headaches
- Liver tumors, benign or malignant, or liver disease
- Undiagnosed abnormal uterine bleeding
- Pregnancy, because there is no reason to use COCs during pregnancy
- Breast cancer or other estrogen- or progestin-sensitive cancer, now or in the past
- Use hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, due to the potential for ALT elevations

#### **WARNINGS AND PRECAUTIONS**

- Thrombotic and other vascular events Stop COCs if an arterial or venous thrombotic event occurs,
  or 4 weeks before through 2 weeks after major surgery 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). Start COCs no earlier than 4 weeks after delivery, in women who are not breastfeeding.
   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 because breast cancer is a hormonally-sensitive tumor.
- Liver disease Discontinue COCs if jaundice develops. Hepatic adenomas and very rare hepatocellular
  carcinomas are associated with long-term (>8 years) of COC use. Do not use in women receiving hepatitis
  C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, due to the
  potential for ALT elevations.
- 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 gallbladder disease, carbohydrate and lipid metabolic
  effects, headache, bleeding irregularities including amenorrhea, COC use before and during pregnancy,
  depression, interference with laboratory tests, hereditary angioedema, and chloasma.

#### **ADVERSE REACTIONS**

The most serious reactions are discussed elsewhere in the labeling and include serious cardiovascular events, 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.

IMPORTANT SAFETY INFORMATION for Tarina® 24 Fe (norethindrone acetate and ethinyl estradiol tablets, USP, and ferrous fumarate tablets, 1 mg/20 mcg and 75 mg)<sup>9</sup>

#### INDICATIONS

Tarina 24 Fe is indicated for use by women to prevent pregnancy. The efficacy of Tarina 24 Fe in women with a body mass index (BMI) of greater than 35 kg/m² has not been evaluated.

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

Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptives (COC) use. This risk increases with age, particularly in women over 35 years of age, and with the number of cigarettes smoked. For this reason, COCs should not be used by women who are over 35 years of age and smoke.

Consult the Package Insert or <u>click here</u> for Complete Prescribing Information

#### CONTRAINDICATIONS

Do not prescribe Tarina 24 Fe to women who are known to have the following conditions:

- A high risk of arterial or venous thrombotic diseases. Examples include women who are known to:
   Smoke, if over age 35
- o Have deep vein thrombosis or pulmonary embolism, now or in the past
- O Have inherited or acquired hypercoagulopathies

- o Have cerebrovascular disease
- O Have coronary artery disease
- Have thrombogenic valvular or thrombogenic rhythm diseases of the heart (for example, subacute bacterial endocarditis with valvular disease, or atrial fibrillation)
- O Have uncontrolled hypertension
- O Have diabetes mellitus with vascular disease
- Have headaches with focal neurological symptoms or migraine headaches with aura or women over age 35 with any migraine headaches
- Liver tumors, benign or malignant, or liver disease
- Undiagnosed abnormal uterine bleeding
- Pregnancy, because there is no reason to use COCs during pregnancy
- Breast cancer or other estrogen- or progestin-sensitive cancer, now or in the past
- Use hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, due to the potential for ALT elevations

#### WARNINGS AND PRECAUTIONS

- Thrombotic and other vascular problems Stop Tarina 24 Fe if an arterial or venous thrombotic
  event occurs, or 4 weeks before through 2 weeks after major surgery 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). Start Tarina 24 Fe no earlier than 4 weeks after delivery, in women
  who are not breastfeeding. Combined oral contraceptives should be used with caution in women with
  cardiovascular risk factors.
- Liver disease Discontinue COCs if jaundice develops. Hepatic adenomas and very rare hepatocellular
  carcinomas are associated with long-term (>8 years) of COC use. Do not use in women receiving hepatitis
  C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, due to the
  potential for ALT elevations.
- 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, depression, interference with laboratory tests, hereditary
  angioedema, and chloasma.

#### **ADVERSE REACTIONS**

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

Patients should be counseled that Tarina 24 Fe does not protect against HIV infection (AIDS) and other sexually transmitted diseases.



# IMPORTANT SAFETY INFORMATION for Jasmiel® (drospirenone and ethinyl estradiol tablets, USP 3.0 mg/0.02 mg)<sup>10</sup>

#### **INDICATIONS**

Jasmiel is indicated for use by women to prevent pregnancy. Jasmiel is indicated for the treatment of symptoms of premenstrual dysphoric disorder (PMDD) for women who choose to use an oral contraceptive for contraception. Jasmiel is indicated for the treatment of moderate acne for women at least 14 years old and have achieved menarche, only if the patient desires an oral contraceptive for birth control.

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

Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptive (COC) use. This risk increases with age, particularly in women over 35 years of age, and with the number of cigarettes smoked. For this reason, COCs are contraindicated in women who are over 35 years of age and smoke.

# Consult the Package Insert or <u>click here</u> for Complete Prescribing Information

#### **CONTRAINDICATIONS**

Do not prescribe Jasmiel to women who are known to have the following:

- Renal impairment
- Adrenal insufficiency
- A high risk of arterial or venous thrombotic diseases. Examples include women who are known to:
- o Smoke, if over age 35
- O Have deep vein thrombosis or pulmonary embolism, now or in the past
- o Have inherited or acquired hypercoagulopathies
- o Have cerebrovascular disease
- O Have coronary artery disease
- Have thrombogenic valvular or thrombogenic rhythm diseases of the heart (for example, subacute bacterial endocarditis with valvular disease, or atrial fibrillation)
- O Have uncontrolled hypertension
- O Have diabetes mellitus with vascular disease
- O Have headaches with focal neurological symptoms or migraine headaches with aura or women over age 35 with any migraine headaches
- Undiagnosed abnormal uterine bleeding
- Breast cancer or other estrogen- or progestin-sensitive cancer, now or in the past
- Liver tumors, benign or malignant, or liver disease
- Pregnancy, because there is no reason to use COCs during pregnancy
- Use of hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, due to the potential for ALT elevations

#### WARNINGS AND PRECAUTIONS

- Thrombotic and other vascular problems Stop Jasmiel if an arterial or venous thrombotic event occurs, or at least 4 weeks before through 2 weeks after major surgery 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). Start Jasmiel no earlier than 4 weeks after delivery, in women who are not breastfeeding. COCs containing drospirenone (DRSP) may be associated with a higher risk of venous thromboembolism (VTE) than COCs containing other progestins. Before initiating Jasmiel in a new COC user or a woman who is switching from a contraceptive that does not contain DRSP, consider the risks and benefits of a DRSP-containing COC in light of her risk of a VTE.
- Hyperkalemia DRSP has anti-mineralocorticoid activity. Do not use in patients predisposed to
  hyperkalemia. Check serum potassium concentration during the first treatment cycle in women on
  long-term treatment with medications that may increase serum potassium concentration.
- Carcinoma of the breasts and reproductive organs Women with currently have or have had breast cancer should not use Jasmiel because breast cancer is a hormonally-sensitive tumor.
- Liver disease Discontinue COCs if jaundice develops. Hepatic adenomas and very rare
  hepatocellular carcinomas are associated with long-term (>8 years) of COC use. Do not use in
  women receiving hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or
  without dasabuvir, due to the potential for ALT elevations.
- 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, COC use before and during pregnancy, depression,
  interference with laboratory tests, hereditary angioedema, and chloasma.

#### **ADVERSE REACTIONS**

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

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

# IMPORTANT SAFETY INFORMATION for Lyleq® (norethindrone tablets USP, 0.35 mg)<sup>11</sup> INDICATIONS

Lyleg, a progestin-only oral contraceptive, is indicated for the prevention of pregnancy.

#### WARNING

Cigarette smoking greatly increases the possibility of suffering heart attacks and strokes. Women who use oral contraceptives are strongly advised not to smoke.

# Consult the Package Insert or <u>click here</u> for Complete Prescribing Information 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 AND PRECAUTIONS

- Ectopic pregnancy Up to 10% of pregnancies reported in clinical studies of progestin-only oral
  contraceptive users are extrauterine. Health providers should be alert to the possibility of an ectopic
  pregnancy in women who become pregnant or complain of lower abdominal pain while on progestinonly oral contraceptives.
- 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. Rarely, these may twist or rupture, requiring surgical intervention.
- Irregular genital bleeding
- Hepatic neoplasia Hepatic adenomas and very rare hepatocellular carcinomas are associated
  with COC use. There is insufficient data to determine whether POP use increases the risk of
  developing hepatic neoplasia.
- Other warnings and precautions include carbohydrate and lipid metabolic effects, drug interactions, lactation, headache, interference with laboratory tests.

#### **ADVERSE REACTIONS**

Commonly reported adverse reactions include irregular bleeding, dizziness, nausea, breast tenderness, headache, acne, gastrointestinal effects, hirsutism, and weight gain.

Patients should be counseled that oral contraceptives do not protect against transmission of HIV (AIDS) and other sexually transmitted diseases such as chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.



# IMPORTANT SAFETY INFORMATION for medroxyPROGESTERone acetate injectable suspension, USP (150 mg/mL for intramuscular use only)<sup>1</sup>

#### INDICATIONS

MedroxyPROGESTERONEone acetate injectable suspension is a progestin indicated for use by females of reproductive potential to prevent pregnancy. <u>Limitations of Use</u>: The use of medroxyPROGESTERONEone acetate injectable suspension is not recommended as a long-term (i.e., longer than 2 years) birth control method unless other options are considered inadequate.

#### WARNING: LOSS OF BONE MINERAL DENSITY

- Women who use medroxyPROGESTERONEone acetate injectable suspension may lose significant bone mineral density. Bone loss is greater with increasing duration of use and may not be completely reversible.
- It is unknown if use of medroxyPROGESTERONEone acetate injectable suspension during adolescence or early adulthood, a critical period of bone accretion, will reduce peak bone mass and increase the risk for osteoporotic fracture in later life.
- MedroxyPROGESTERONEone acetate injectable suspension is not recommended as a long-term birth control method (i.e., longer than 2 years) unless other birth control methods are considered inadequate.

# Consult the Package Insert or <u>click here</u> for Complete Prescribing Information CONTRAINDICATIONS

The use of medroxyPROGESTERONEone acetate injectable suspension is contraindicated in the following conditions:

- Known or suspected pregnancy or as a diagnostic test for pregnancy
- Active thrombophlebitis, or current or past history of thromboembolic disorders, or cerebral vascular disease
- Known or suspected malignancy of breast
- Known hypersensitivity to medroxyPROGESTERONEone acetate injectable suspension or any
  of its other ingredients
- Significant liver disease
- Undiagnosed vaginal bleeding

#### **WARNINGS AND PRECAUTIONS**

- Loss of bone mineral density Use of medroxyPROGESTERONEone acetate injectable
  suspension reduces serum estrogen levels and is associated with significant loss of bone mineral
  density (BMD). This loss of BMD is of particular concern during adolescence and early adulthood,
  a critical period of bone accretion. It is unknown if use of medroxyPROGESTERONEone acetate
  injectable suspension by younger women will reduce peak bone mass and increase the risk for
  osteoporotic fracture in later life.
- Thromboembolic disorders Discontinue medroxyPROGESTERONEone acetate injectable suspension
  in patients who develop thrombosis unless she has no other acceptable options for birth control.
- Cancer risks Women who have or have had a history of breast cancer should not use
  hormonal contraceptives, including medroxyPROGESTERONEone acetate injectable suspension,
  because breast cancer may be hormonally sensitive. Women with a strong family history of breast
  cancer should be monitored with particular care.
- Ectopic pregnancy Be alert to the possibility of an ectopic pregnancy among women using medroxyPROGESTERONEone acetate injectable suspension who become pregnant or complain of severe abdominal pain.
- Anaphylaxis and anaphylactoid reactions Anaphylaxis and anaphylactoid reaction have been reported with the use of medroxyPROGESTERONEone acetate injectable suspension. Institute emergency medical treatment if an anaphylactic reaction occurs.
- Liver function Discontinue medroxyPROGESTERONEone acetate injectable suspension if iaundice or disturbances of liver function develop.
- Other warnings and precautions include convulsions, carbohydrate and lipid metabolic
  effects, depression, weight gain, bleeding irregularities including amenorrhea, COC use before
  and during pregnancy, lactation, interference with laboratory tests.

#### **ADVERSE REACTIONS**

The most serious reactions are discussed elsewhere in the labeling and include loss of bone mineral density, thromboembolic disease, breast cancer, and anaphylaxis. Commonly reported adverse reactions include irregular uterine bleeding, abdominal pain/discomfort, weight gain, dizziness, headache, nervousness, and decreased libido.

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

# PRODUCT INFORMATION FOR EContra One-Step® (levonorgestrel tablet, 1.5 mg)12

#### INDICATION

EContra One-Step is a progestin-only emergency contraceptive pill for use in women to reduce the chance of pregnancy after unprotected sex (if contraceptive failed or birth control not used). EContra One-Step is not intended to be used in place of routine birth control.

#### Consult the Package Insert or <u>click here</u> for Drug Label Information

#### WARNING

- Allergy alert Do not use if you have ever had an allergic reaction to levonorgestrel.
- Sexually transmitted diseases (STDs) alert This product does not protect against HIV/ AIDS or other STDs.
- Pregnancy alert Do not use if you are already pregnant (because it will not work).
- Interaction with other medications Women should ask a doctor or pharmacist before using EContra One-Step if taking efavirenz (HIV medication) or rifampin (tuberculosis treatment) or medication for seizures (epilepsy). These medications may reduce the effectiveness of levonorgestrel.

#### **ADVERSE REACTIONS**

Commonly reported adverse reactions include menstrual changes, abdominal pain, nausea, vomiting, tiredness, headache, dizziness, or breast pain.

#### References:

- MedroxyPROGESTERONEone acetate injectable suspension prescribing information. Charleston SC, USA: Afaxys Pharma, LLC; 2020.
- 2. Aubra EQ prescribing information, Charleston SC, USA: Afaxys Pharma, LLC; 2021.
- 3. Chateal EQ prescribing information, Charleston SC, USA: Afaxys Pharma, LLC; 2021.
- 4. Cyred EQ prescribing information, Charleston SC, USA: Afaxys Pharma, LLC; 2021.
- 5. Tarina Fe 1/20 EQ prescribing information, Charleston SC, USA: Afaxys Pharma, LLC; 2021.
- 6. Tri-VyLibra prescribing information, Charleston SC, USA: Afaxys Pharma, LLC; 2021.
- 7. Tri-VyLibra Lo prescribing information, Charleston SC, USA: Afaxys Pharma, LLC; 2021.
- 8. VyLibra prescribing information, Charleston SC, USA: Afaxys Pharma, LLC; 2021.
- 9. Tarina 24 Fe prescribing information, Charleston SC, USA: Afaxys Pharma, LLC; 2021.
- 10. Jasmiel prescribing information, Charleston SC, USA: Afaxys Pharma, LLC; 2021.
- 11. Lyleq prescribing information, Charleston SC, USA: Afaxys Pharma, LLC; 2021.
- 12. EContra One-Step product information, Charleston SC, USA: Afaxys Pharma, LLC, 2020.



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To report SUSPECTED ADVERSE REACTIONS for any of these products, call 1-855-888-2467 or report via the FDA MedWatch Program at www.fda.gov/medwatch or 1-800-FDA-1088.

Go to AfaxysPharma.com to find your authorized distributor and to obtain pricing.

Your Mission Is Our Mission.