<table>
<thead>
<tr>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activities and relationships with others. Diagnosis is made by healthcare providers according to DSM-5.</td>
</tr>
<tr>
<td>Physical symptoms associated with irritability. Other features include decreased interest in usual activities, difficulty concentrating, lack of energy, change in appetite or sleep, and feeling out of control.</td>
</tr>
</tbody>
</table>

**TREATMENT OPTIONS**

- **Drospirenone and ethinyl estradiol tablets** are also indicated for use by women to prevent pregnancy.
- **PMDD** is an estrogen/progestin COC, indicated for use by women to:
  - Treat symptoms of PMDD for women who choose to use an oral contraceptive for contraception and acne.
  - Prevent pregnancy.

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

Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptive (COC) use. Women over 35 years old who smoke should not use drospirenone and ethinyl estradiol tablets.

**ADVERSE REACTIONS**

- The most frequent adverse reactions (2% or greater) in PMDD clinical trials were:
  - Menstrual irregularities (24.9%)
  - Nausea/vomiting (4.2%)
- The most frequent adverse reactions (greater than or equal to 2%) in contraception and acne clinical trials were:
  - Breast pain/tenderness (4.0%)

**INDICATIONS AND USAGE**

- **PMDD** is an estrogen/progestin COC, indicated for use by women to:
  - Treat symptoms of PMDD for women who choose to use an oral contraceptive for contraception and acne.
  - Prevent pregnancy.
2.3 How to Take Drospirenone and Ethinyl Estradiol Tablets:

Take one tablet by mouth at the same time every day. The tablets are to be taken under fasting conditions (at least 1 hour before or 2 hours after eating) unless otherwise directed by your healthcare provider. Drospirenone and ethinyl estradiol tablets can be taken with or without food.

2.4 What to Do If You Miss a Tablet:

If you miss a tablet, your contraceptive effectiveness may be temporarily decreased. If you miss a tablet, you should take it as soon as you remember it. If you do not remember until later in the day, take it with your dinner. If you forget to take a tablet and remember more than 12 hours later, or the next day, you should use a backup contraceptive method for the next 7 days.

2.5 If You Need to Stop Taking Drospirenone and Ethinyl Estradiol Tablets:

Stop drospirenone and ethinyl estradiol tablets if an arterial or venous thrombotic (VTE) event occurs. Drospirenone and ethinyl estradiol tablets are not recommended for women with a history of thrombosis or thromboembolism.

2.6 If You Get Pregnant While Taking Drospirenone and Ethinyl Estradiol Tablets:

If you become pregnant while taking drospirenone and ethinyl estradiol tablets, stop taking them and use an alternative contraceptive method. The risk of pregnancy associated with use of contraceptives is not reduced, regardless of the contraceptive method used. When switching from another contraceptive method, the patient should consult with her healthcare provider to determine an appropriate alternative contraceptive method.

2.7 If You Need to Change to a Different Method of Contraception:

When switching from another contraceptive method, the patient should consult with her healthcare provider to determine an appropriate alternative contraceptive method.

3.0 Contraindications:

Drospirenone and ethinyl estradiol tablets are contraindicated for use in any woman with the following conditions:

- Hypersensitivity to drospirenone or ethinyl estradiol
- Known or suspected pregnancy
- Known or suspected lactation
- Known or suspected breast cancer
- Known or suspected estrogen-dependent neoplasms
- Known or suspected liver tumors, benign or malignant, or liver disease
- Known or suspected pregnancy
- Known or suspected lactation
- Known or suspected breast cancer
- Known or suspected estrogen-dependent neoplasms
- Known or suspected liver tumors, benign or malignant, or liver disease
- Known or suspected pregnancy
- Known or suspected lactation
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- Known or suspected pregnancy
- Known or suspected lactation
- Known or suspected breast cancer
- Known or suspected estrogen-dependent neoplasms
- Known or suspected liver tumors, benign or malignant, or liver disease

3.1Warnings and Precautions:

- VTE Risk:
  - Women with a personal or family history of idiopathic VTE or DVT, or a personal or family history of inherited or acquired hypercoagulability may have an increased risk of VTE.
  - Women with a personal or family history of arterial thrombosis (including MI, stroke, or transient ischemic attack) may have an increased risk of arterial events.
  - Women with a history of thrombosis or thromboembolism should not use drospirenone and ethinyl estradiol tablets.
  - Women with a history of arterial or venous thrombotic events should be monitored closely for recurrence.

- Acne:
  - Acne may occur at any time during contraceptive use, including during the first month of use.
  - Acne may be transient and of no consequence. If the patient misses one or more white tablets, she should still be prescribed a new dose of tablets at the end of the first month of use.

- Breastfeeding:
  - Breastfeeding is not recommended for women taking drospirenone and ethinyl estradiol tablets.
  - The patient should consult with her healthcare provider to determine an appropriate alternative contraceptive method.

- Renal and Hepatic Function:
  - Women with pre-existing renal or hepatic impairment should consult with their healthcare provider to determine an appropriate alternative contraceptive method.

- Hepatitis C:
  - Women with hepatitis C should consult with their healthcare provider to determine an appropriate alternative contraceptive method.

- Hepatitis B:
  - Women with hepatitis B should consult with their healthcare provider to determine an appropriate alternative contraceptive method.

- Diabetes:
  - Women with diabetes should consult with their healthcare provider to determine an appropriate alternative contraceptive method.

- Hypertension:
  - Women with hypertension should consult with their healthcare provider to determine an appropriate alternative contraceptive method.

- Cardiovascular Disease:
  - Women with a history of cardiovascular disease should consult with their healthcare provider to determine an appropriate alternative contraceptive method.

- Migraine:
  - Women with a history of migraine should consult with their healthcare provider to determine an appropriate alternative contraceptive method.

- Glaucoma:
  - Women with glaucoma should consult with their healthcare provider to determine an appropriate alternative contraceptive method.

- Breast Cancer:
  - Women with a history of breast cancer should consult with their healthcare provider to determine an appropriate alternative contraceptive method.

- Estrogen-Dependent Neoplasms:
  - Women with a history of estrogen-dependent neoplasms should consult with their healthcare provider to determine an appropriate alternative contraceptive method.

- Erythrocytosis:
  - Women with a history of erythrocytosis should consult with their healthcare provider to determine an appropriate alternative contraceptive method.

- Breastfeeding:
  - Breastfeeding is not recommended for women taking drospirenone and ethinyl estradiol tablets.
  - The patient should consult with her healthcare provider to determine an appropriate alternative contraceptive method.

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  - Women with a history of estrogen-dependent neoplasms should consult with their healthcare provider to determine an appropriate alternative contraceptive method.

- Erythrocytosis:
  - Women with a history of erythrocytosis should consult with their healthcare provider to determine an appropriate alternative contraceptive method.

3.2 Interactions:

Drospirenone and ethinyl estradiol tablets may interact with other medications or supplements. Women should consult with their healthcare provider to determine an appropriate alternative contraceptive method.

3.3 Dosage and Administration:

Drospirenone and ethinyl estradiol tablets are available in 2 colors:

- Pink tablets: 1 mg drospirenone and 3 mg ethinyl estradiol
- White tablets: 1 mg drospirenone and 0.03 mg ethinyl estradiol

Drospirenone and ethinyl estradiol tablets should be stored at room temperature (15°C to 30°C) and protected from light.

A summary of the potential risks of VTE for users of drospirenone and ethinyl estradiol tablets in women taking estrogen-containing contraceptives is provided in Table 1.
women with a history of COC-related cholestasis may have the condition recur with COC use. However, the attributable risk of liver cancers in COC users is less than one case per 100,000.

Studies have shown an increased risk of developing hepatocellular carcinoma in long-term (>8 years) COC users. However, COC causation has been excluded.

Acute or chronic disturbances of liver function may necessitate the discontinuation of COC use until markers of liver function return to normal. Poorly metabolized drugs (e.g., clarithromycin, itraconazole, voriconazole), HIV/HCV protease inhibitors (e.g., indinavir, boceprevir), and strong CYP3A4 inhibitors (e.g., ketoconazole) can increase the risk of hyperkalemia in high-risk patients who take a strong CYP3A4 inhibitor concomitantly. Monitoring serum potassium concentration in high-risk patients who take a strong CYP3A4 inhibitor concomitantly is recommended.

Patients with conditions that predispose to hyperkalemia (that is, renal impairment, hepatic impairment, hyperparathyroidism, myasthenia gravis, acute or chronic renal failure) should have their serum potassium concentration checked during the first treatment cycle. Medications that may increase serum potassium concentration should have their serum potassium concentration checked during the first treatment cycle. Medications that may increase serum potassium concentration should have their serum potassium concentration checked during the first treatment cycle. Medications that may increase serum potassium concentration should have their serum potassium concentration checked during the first treatment cycle.

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5.6 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

6. ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reactions observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

6.2 Depression

Women with a history of depression should be carefully observed and drospirenone and ethinyl estradiol tablets considered for discontinuation in case of depression.

6.3 Migrainous headache

An increase in frequency or severity of migraine during COC use (which may be prodromal of a vascular event) is an indication to discontinue drospirenone and ethinyl estradiol tablets.

6.4 Breast tenderness

Breast tenderness has been observed most frequently during the first three months of COC use and tends to decrease with continued use of COCs.

6.5 Nausea

Nausea is generally mild and self-limiting.

6.6 Vascular events

Vascular events with COCs include deep vein thrombosis, pulmonary embolism, and cerebrovascular accidents.

6.7 Gallbladder disease

Gallbladder disease includes acute cholecystitis and cholelithiasis.

6.8 Carbohydrate and lipid metabolic effects

Women who are obese, have diabetes mellitus, have impaired glucose metabolism, or who are at high risk for carbohydrate and lipid metabolic disorders, may be at increased risk of metabolic disturbances with use of COCs.

6.9 Pregnancy

Women who use oral contraceptives prior to pregnancy should be instructed to notify the prescriber if they plan to become pregnant or intend to nurse.

6.10 Non-contraceptive indications

Non-contraceptive indications include the use of COCs for the treatment of dysmenorrhea, acne, and certain conditions such as menorrhagia, hirsutism, and PCOS.

6.11 COC Use Before or During Early Pregnancy

Extensive epidemiological studies have revealed no increased risk of birth defects in women who have used oral contraceptives prior to pregnancy. Studies also do not suggest a teratogenic effect of COCs in women who have already conceived.

6.12 Other Conditions

COCs should not be used in women with a tendency to chloasma (e.g., skin darkening or pigmentation). Women with a history of hypertension, hypertriglyceridemia, hepatic dysfunction, serious depression, or migraine with aura should be observed carefully.

6.13 Drug Interactions

Drug interactions are described elsewhere in the Warnings and Precautions section.

6.14 Monitoring

Women using COCs should be instructed to observe the warning signs of threatened or established deep vein thrombosis, pulmonary embolism, and cerebrovascular accidents.

6.15 Safety and Risk-Benefit Considerations

Safety and risk-benefit considerations are described elsewhere in the Warnings and Precautions section.

7. DRUG INTERACTIONS

7.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

There is no evidence of impaired fertility associated with drospirenone and ethinyl estradiol tablets.

7.2 Other Drugs

The concomitant use of drospirenone and ethinyl estradiol tablets with other drug products with a strong potential for depression of the P450 3A4 enzyme system may be contraindicated, including but not limited to, furazolidone, ketoconazole, troleandomycin, clarithromycin, macrolide antibiotics, ketocazole, ritonavir, and indinavir.

7.3 Pregnancy

Pregnancy should be excluded before starting therapy, and pregnancy test should be performed in all patients before starting treatment with drospirenone and ethinyl estradiol tablets.

7.4 Nursing Mothers

Women who are breast feeding should be instructed to notify their prescriber if they plan to breast feed or intend to nurse.

7.5 Pediatric use

There is no information on the use of drospirenone and ethinyl estradiol tablets in pediatric populations.

7.6 Geriatric Use

Geriatric use is described elsewhere in the Geriatric Use section.

7.7 Administration and Dosage

Administration and dosage are described elsewhere in the Directions for Use section.

7.8 Conditions of Approval

Conditions of approval are described elsewhere in the Conditions of Approval section.

8. COMMONLY REPORTED ADVERSE REACTIONS

The following adverse reactions, described elsewhere in the Adverse REACTIONS section, are commonly reported adverse reactions.

9. OVERDOSAGE

There is no information on the use of drospirenone and ethinyl estradiol tablets in overdose situations.

10. SELECTION OF THE DRUG

Selection of the drug is described elsewhere in the Selection of the Drug section.

11. PATIENT INFORMATION

Patient information is described elsewhere in the Patient Information section.
The structural formulas are as follows:

The inert film coated tablets contain titanium dioxide, polydextrose, hypromellose, triacetin, polysorbate 80, lactose monohydrate, magnesium stearate and pregelatinized starch. 

The inactive ingredients in the pink tablets are titanium dioxide, macrogol/PEG 3350 NF, talc, lecithin side and ".

Drospirenone and ethinyl estradiol tablets contain 24 round pink tablets, and 4 round white tablets in a

Serum concentrations of synthetic steroids.

The inactive ingredients in the pink tablets are titanium dioxide, macrogol/PEG 3350 NF, talc, lecithin side and ".

Contraindications (4)

Drospirenone and ethinyl estradiol tablets contain 24 round pink tablets, and 4 round white tablets in a
1.39-fold (90% CI: 1.28, 1.52) for DRSP and EE, respectively. Although no clinically relevant effects were seen in a clinical drug-drug interaction study conducted in 20 premenopausal women, co-administration of acetaminophen may increase plasma EE concentrations, possibly by inhibition of conjugation. In a study including CYP3A4, acetaminophen may decrease the effectiveness of COCs or increase breakthrough bleeding.

3.4.5 Effects of Other Drugs on Combined Oral Contraceptives

The mean exposure to DRSP in women with moderate liver impairment is approximately three times higher than in healthy women (CLcr of 50–79 mL/min vs. CLcr > 80 mL/min; Table 2). This increase is clinically relevant, with a corresponding nearly threefold increase in serum DRSP concentrations, as shown in Table 2. For EE, steady-state conditions are reported during the second half of a treatment cycle. Following oral administration of EE, mean plasma EE AUC (0–24 h) values were comparable to those in the control group with CLcr > 80 mL/min. The serum DRSP and EE concentrations in the group with CLcr of 50–79 mL/min were comparable to those in the group with CLcr of 30–49 mL/min, whereas the serum DRSP concentration in the group with CLcr of 30–49 mL/min was higher than in the control group with CLcr > 80 mL/min.

3.6 Renal Impairment

For EE, steady-state conditions are reported during the second half of a treatment cycle. Following oral administration of EE, mean plasma EE AUC (0–24 h) values were comparable to those in the control group with CLcr > 80 mL/min. The serum DRSP and EE concentrations in the group with CLcr of 50–79 mL/min were comparable to those in the group with CLcr of 30–49 mL/min, whereas the serum DRSP concentration in the group with CLcr of 30–49 mL/min was higher than in the control group with CLcr > 80 mL/min.

3.7 Pregnancy

Drospirenone and ethinyl estradiol tablets have not been studied in postmenopausal women and no data are available in women over the age of 55 years.

3.8 Nursing Mothers

It is not known whether DRSP and EE are excreted in human milk. Because many drugs are excreted in human milk, and because of the potential for adverse reactions in nursing infants, a decision should be made whether to discontinue the drug or to discontinue breastfeeding.

4.6.7 Pseudovaginitis

Pseudovaginitis, caused by a high level of estrogen exposure, is a common side effect of COCs. It is characterized by increased vaginal secretion, which can resemble vaginitis. Pseudovaginitis is more common in the first few months of COC use, but it can persist for several years. It is usually self-limiting and resolves when the COC is discontinued. However, it can be bothersome to some women and may require treatment with antifungal or symptomatic medications.

4.7.1 Effects of Other Drugs on Combined Oral Contraceptives

The use of COCs may affect the effectiveness of other drugs. For example, the COC may increase the risk of bleeding or breakthrough bleeding. The COC may also affect the effectiveness of other drugs, such as anticoagulants, by interfering with their metabolism or excretion.

4.8 Drug Interactions

Drug interactions are common with combined oral contraceptives containing estrogen and progestogen. The potential for drug interactions between the estrogen and progestogen components of COCs is well recognized. Drug interactions can occur when COCs are used concomitantly with other medications, such as anticoagulants, antibiotics, and other hormonal contraceptives. Drug interactions can also occur when COCs are used with other medications, such as antidepressants, antihypertensives, and immunosuppressants. Drug interactions can result in increased or decreased drug efficacy, increased or decreased drug toxicity, or new drug interactions.

The potential for drug interactions with COCs is significant, and careful consideration should be given to any planned or concurrent use of medications that may affect the contraceptive effectiveness of COCs. The potential for drug interactions should be considered when selecting a COC regimen, and patients should be advised to inform their healthcare provider of all medications they are taking, including over-the-counter medications and herbal supplements.
Drospirenone and ethinyl estradiol tablets are available in the following packaging configuration:

Each blister card contains, in the following order, 24 pink tablets and 4 white tablets. Each round,

biconvex, pink tablet (debossed with “Z3” on one side) contains 3 mg drospirenone (DRSP) and 0.02 mg

Each blister card contains, in the following order, 24 pink tablets and 4 white tablets. Each round,

biconvex, pink tablet (debossed with “Z3” on one side) contains 3 mg drospirenone (DRSP) and 0.02 mg

Drospirenone and ethinyl estradiol tablets contain 28 tablets in a blister card (NDC 75834-116-84).

Two additional clinical drug interaction studies using ranitidine and simvastatin as single substances for

COCs were each performed in 16 healthy postmenopausal women. The results of these studies demonstrated the plasma-pharmacokinetics of the COC tablet/patch were not influenced by use of COC containing 28 tablets containing 3 mg of DRSP and 0.02 mg of EE.

in vitro and in vivo studies DRSP did not affect turnover of model substrates of CYP2C19, CYP3A4, and CYP1A2, with CYP2C19 being the major metabolizing enzyme. In vitro and in vivo studies showed no significant influence on the turnover of model substrates of CYP2C9 or CYP1A1. A study was conducted using pharmacokinetic profile in 12 women who took COCs containing 3 mg of DRSP and 0.02 mg of EE for 14 days. No significant inhibition of CYP2C19 was observed.

The study was conducted using the MEGA co-enrolled database and showed that the use of dienogest-containing COCs was associated with a significantly higher risk of MI in women aged 35 years or younger during cycles in which no other form of contraception was used.

There have been reports of pregnancy while taking hormonal contraceptives and antibiotics,

Interactions with Drugs That Have the Potential for an Increase in Serum Potassium Concentration

Menstrual Cycle

Study 1

Study 2

Study 3

Study 2

Table 4: Efficacy Results by Age and Ethnicity

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<th>Age Group</th>
<th>Placebo</th>
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<td>0.13%</td>
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<td>30-39</td>
<td>0.17%</td>
<td>0.16%</td>
<td>0.16%</td>
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<td>0.14%</td>
<td>0.14%</td>
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<table>
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<tr>
<th>BMI (&lt;30)</th>
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</tr>
<tr>
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<table>
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<th>320mg</th>
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<tbody>
<tr>
<td>White</td>
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<td>0.12%</td>
<td>0.11%</td>
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<tr>
<td>African</td>
<td>0.15%</td>
<td>0.14%</td>
<td>0.13%</td>
</tr>
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</table>

15. REFERENCES


3. Combined Hormonal Contraceptives (CHCs) and the Risk of Cardiovascular Endpoints. Sidney, S.

4. Combined Hormonal Contraceptives (CHCs) and the Risk of Cardiovascular Endpoints. Sidney, S.


2. Look at Your Pill Pack – It has 28 Pills

The drospirenone and ethinyl estradiol tablets can be taken without regard to meals, the same time every day, preferably after the evening meal or at bedtime, with some liquid, as needed.

It is important to take drospirenone and ethinyl estradiol Tablets in the order directed on the package at the same time every day.

1. Decide What Time of Day You Want to Take Your Pill

Use a back-up method (such as condoms and spermicides) until you check with your healthcare provider.

2. The right way to take the pill is to take one pill every day at the same time in the order directed on the package. Preferably, take the pill after the evening meal or at bedtime, with some liquid, as needed.

3. The right way to take the pill is to take one pill every day at the same time in the order directed on the package. Preferably, take the pill after the evening meal or at bedtime, with some liquid, as needed.

4. Missing pills can also cause spotting or light bleeding, even when you make up these missed pills. See "WHAT TO DO IF YOU MISS PILLS" if you have diarrhea or if you take certain medicines, including some antibiotics and some herbal products such as St. John's Wort, your pills may not work as intended.

5. If you have vomiting (within 3 to 4 hours after you take your pill), you should follow the instructions in the event pills are missed. See "WHAT TO DO IF YOU MISS PILLS" if you have vomiting (within 3 to 4 hours after you take your pill), you should follow the instructions in the event pills are missed. See "WHAT TO DO IF YOU MISS PILLS" if you have vomiting (within 3 to 4 hours after you take your pill), you should follow the instructions in the event pills are missed.

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*You may take Day Label Stickers, see Where to Start the First Pack of Pills below.

1. You have not had a period in 3 months or more (not due to recent illness or psychological problems).

2. Use the first pink pill of the pack during the first 24 hours of your period.

3. You have not had a period in the 7 days before you start the pill pack.

4. You have not taken any birth control pills in the past 7 days.

5. You have not taken any other form of birth control (such as a condom and spermicide).

6. You have not had a period during the past 2 weeks.

7. You have not had a period during the past 2 months.

8. You have not had a period during the past 6 months.

9. You have not had a period during the past 1 year.

10. You have not had a period during the past 18 months.

11. You have not had a period during the past 2 years.

12. You have not had a period during the past 3 years.

13. You have not taken any other form of birth control (such as a condom and spermicide).

14. You have not had a period during the past 7 days.

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126. You have not had a period during the past 7 days.

127. You have not taken any other form of birth control (such as a condom and spermicide).
Blister Cards of 28 Tablets each.

Drospirenone and ethinyl estradiol tablets

Women who are or may become pregnant must not use this product. Women who use birth control pills may have a slightly higher chance of getting cervical cancer. Birth control pills do not seem to cause breast cancer. However, if you have breast cancer now, or have had breast cancer in the past, the pill may not be right for you. Women who use birth control pills, for women who are not pregnant and do not use birth control pills, for women who are pregnant and use birth control pills are followed for your breast health and to check for any breast problems. It is important to continue taking your birth control pills even if you are pregnant. Stop taking drospirenone and ethinyl estradiol tablets if you are pregnant.

Breast Cancer

Other drugs may affect the use of birth control pills, including prescription and over-the-counter medicines, vitamins, and herbal products. Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal products.

What are the Most Common Types of Birth Control Pills?

Talk with your healthcare provider about your risk of getting a blood clot before deciding which birth control pill is right for you. It is possible to die or be permanently disabled from a problem caused by a blood clot, such as a heart attack or a stroke. Some examples of serious clot are listed below:

- Deep vein thrombosis (DVT)
- Pulmonary embolism (PE)
- Blood in the stool
- Stroke

Side Effects

General Advice about Drospirenone and Ethinyl Estradiol Tablets

If you have concerns or questions, ask your healthcare provider. You may also ask your healthcare provider for more detailed lab data to evaluate medical performance.

NIVAGEN PHARMACEUTICALS

Rx only

NDC 75834-116-29

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

MANUFACTURED BY: Novast Laboratories Ltd.
Toll Free 1-877-977-0687
Sacramento, CA 95827

WHAT SHOULD I KNOW ABOUT MY PERIOD WHEN TAKING DROSPIRENONE AND ETHINYL ESTRADIOL TABLETS?

WHAT IF I WANT TO BECOME PREGNANT?

WHAT IF I MISS MY SCHEDULED PERIOD WHEN TAKING DROSPIRENONE AND ETHINYL ESTRADIOL TABLETS?

WHAT IF I MISS MY REGULAR PERIOD?

WHAT IF I MISS MY REGULAR PERIOD?

WHAT IF I MISS MY REGULAR PERIOD?

WHAT IF I MISS MY REGULAR PERIOD?
Nivagen Pharmaceuticals, Inc.

DROSPIRENONE AND ETHINYL ESTRADIOL

Product Information

Product Type: HUMAN PRESCRIPTION DRUG
Item Code (Source): NDC:75834-116

Packaging

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<tr>
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<th>Item Code</th>
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Quantity of Parts

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Route of Administration

ORAL

Active Ingredient/Active Moiety

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<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
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<tbody>
<tr>
<td>DROSPIRENONE</td>
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<tr>
<td>ETHINYL ESTRADIOL</td>
<td>(ETHINYL ESTRADIOL - UNII:423D2T571U)</td>
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Inactive Ingredients

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<td>FD&amp;C RED NO. 40</td>
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<tr>
<td>FD&amp;C YELLOW NO. 6</td>
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<tr>
<td>FERRIC OXIDE YELLOW</td>
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<tr>
<td>LACTOSE MONOHYDRATE</td>
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<tr>
<td>LECITHIN, SOYBEAN</td>
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</tr>
<tr>
<td>MAGNESIUM STEARATE</td>
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<td>POLYETHYLENE GLYCOL, UNSPECIFIED</td>
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<tr>
<td>POLYSORBATE 80</td>
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</tr>
<tr>
<td>POLYVINYL ALCOHOL</td>
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<td>TALC</td>
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<td>TITANIUM DIOXIDE</td>
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Product Characteristics

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Imprint Code: Z3

Contains

Marketing Information

Marketing Category: ANDA
Application Number or Monograph Citation: ANDA202016
Marketing Start Date: 08/15/2017
Marketing End Date: |

Part 2 of 2

DROSPIRENONE AND ETHINYL ESTRADIOL

Product Information

Product Type: HUMAN PRESCRIPTION DRUG
Item Code (Source): NDC:75834-116

Packaging

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Route of Administration

ORAL

Active Ingredient/Active Moiety

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<tbody>
<tr>
<td>TITANIUM DIOXIDE</td>
<td>(TITANIUM DIOXIDE - UNII:15FIX9V2JP)</td>
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<tr>
<td>POLYDEXTROSE</td>
<td>(POLYDEXTROSE - UNII:VH2XOU12IE)</td>
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<tr>
<td>HYPROMELLOSES</td>
<td>(HYPROMELLOSES - UNII:3NXW29V3WO)</td>
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<tr>
<td>TRIACETIN</td>
<td>(TRIACETIN - UNII:XHX3C3X673)</td>
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<tr>
<td>POLYETHYLENE GLYCOL, UNSPECIFIED</td>
<td>(POLYETHYLENE GLYCOL, UNSPECIFIED - UNII:3WJQ0SDW1A)</td>
<td></td>
</tr>
<tr>
<td>LACTOSE MONOHYDRATE</td>
<td>(LACTOSE MONOHYDRATE - UNII:EWQ57Q8I5X)</td>
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<tr>
<td>MAGNESIUM STEARATE</td>
<td>(MAGNESIUM STEARATE - UNII:70097M6I30)</td>
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<td>STARCH, PREGELATINIZED CORN</td>
<td>(STARCH, PREGELATINIZED CORN - UNII:O8232NY3SJ)</td>
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<td>TALC</td>
<td>(TALC - UNII:7SEV7J4R1U)</td>
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Imprint Code: P;N

Contains

Marketing Information

Marketing Category: ANDA
Application Number or Monograph Citation: ANDA202016
Marketing Start Date: 08/15/2017
Marketing End Date: |

Part 2 of 2

INERT placebo tablet

Product Information

Product Type: HUMAN PRESCRIPTION DRUG
Item Code (Source): NDC:75834-116

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Product Characteristics

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Imprint Code: P;N

Contains

Marketing Information

Marketing Category: ANDA
Application Number or Monograph Citation: ANDA202016
Marketing Start Date: 08/15/2017
Marketing End Date: |

Label

Nivagen Pharmaceuticals, Inc.

Establishment

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Revised: 9/2019