WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS

Smoking increases the risk of thromboembolic disease. Start Blisovi 24 Fe at 17 days after childbirth in women who are over 35 years of age and smoke ≥10 cigarettes per day.

2.3 Missed Tablets

First-trimester:

Blisovi 24 Fe may be started using either a Day 1 start or a Sunday start (see Table 1). For the first 4 days, one brown tablet daily is taken in place of white tablets. Begin each subsequent pack on the same day of the week as the first cycle pack (i.e., on the Sunday after taking the last inactive tablet) and additional non-hormonal contraception is not needed.

Table 1: Instructions for Administration of Blisovi 24 Fe

<table>
<thead>
<tr>
<th>Day 1 start</th>
<th>Sunday start</th>
</tr>
</thead>
<tbody>
<tr>
<td>On the day of removal of an iU or on the day of removal of an implant, inject, or implant additional non-hormonal contraception (such as condoms and a spermicide) within 8 hours.</td>
<td>On the day of removal of an iU or on the day of removal of an implant, inject, or implant additional non-hormonal contraception (such as condoms and a spermicide) within 8 hours.</td>
</tr>
<tr>
<td>On the day when next injection would have been scheduled</td>
<td>On the day when next injection would have been scheduled</td>
</tr>
<tr>
<td>On the day when next insertion would have been scheduled</td>
<td>On the day when next insertion would have been scheduled</td>
</tr>
<tr>
<td>Take the tablet as soon as possible. Take the next pill at the regular time, and continue taking one tablet a day until the pack is finished. Back-up contraception is not needed.</td>
<td>Take the two missed tablets as soon as possible and the next two active tablets the next day. Continue taking one tablet a day until the pack is finished.</td>
</tr>
</tbody>
</table>

After a first-trimester abortion or miscarriage, Blisovi 24 Fe may be started immediately. An additional non-hormonal contraception (such as condoms and a spermicide) must be used to back up the pills for the first 7 days. Back-up contraception is not needed after Day 8 of therapy.

Table 2: Instructions for Administration of Blisovi 24 Fe

<table>
<thead>
<tr>
<th>Day 1 start</th>
<th>Sunday start</th>
</tr>
</thead>
<tbody>
<tr>
<td>On the day of removal of an iU or on the day of removal of an implant, inject, or implant additional non-hormonal contraception (such as condoms and a spermicide) within 8 hours.</td>
<td>On the day of removal of an iU or on the day of removal of an implant, inject, or implant additional non-hormonal contraception (such as condoms and a spermicide) within 8 hours.</td>
</tr>
<tr>
<td>On the day when next injection would have been scheduled</td>
<td>On the day when next injection would have been scheduled</td>
</tr>
<tr>
<td>On the day when next insertion would have been scheduled</td>
<td>On the day when next insertion would have been scheduled</td>
</tr>
<tr>
<td>Take the tablet as soon as possible. Take the next pill at the regular time, and continue taking one tablet a day until the pack is finished. Back-up contraception is not needed.</td>
<td>Take the two missed tablets as soon as possible and the next two active tablets the next day. Continue taking one tablet a day until the pack is finished.</td>
</tr>
</tbody>
</table>

See Full Prescribing Information for complete boxed warning.
6.1 Clinical Trial Experience

Adverse reactions commonly reported by COC users are:

- Nausea
- Headache
- Irregular uterine bleeding
- Breast tenderness
- Vomiting

Other adverse reactions commonly reported in clinical trials included:

- Fatty liver
- Acne
- Weight gain or loss
- Increased or decreased appetite

The safety of Blisovi 24 Fe was evaluated in 743 subjects who participated in an open-label, randomized study, of whom 680 subjects completed a 28-day cycle of treatment with Blisovi 24 Fe. The number of treatment cycles ranged from 1 to 10 cycles, with a median of 3 cycles per subject. A total of 10 subjects (1.3%) discontinued Blisovi 24 Fe due to adverse reactions. The most common adverse reactions leading to discontinuation were headache, nausea, and vomiting. The percentage of women who experienced adverse reactions was generally lower in the second and third cycles compared to the first cycle.

Common Adverse Reactions (≥ 2% of all subjects)

- Body mass index of ≤ 35 kg/m²
- Blood pressure change
- Body weight change

The safety of Blisovi 24 Fe in women with body mass index greater than 35 kg/m² was assessed in 743 women (3,823 28-day cycles). A total of 10 subjects (1.3%) discontinued Blisovi 24 Fe due to adverse reactions. The most common adverse reactions leading to discontinuation were headache, nausea, and vomiting. The percentage of women who experienced adverse reactions was generally lower in the second and third cycles compared to the first cycle.

6.2 Effect on Binding Globulins

COCs may cause changes in binding globulins, which may affect the levels of one or more other medications that a patient may be taking. The magnitude of these effects is generally small, but may be clinically significant for some medications. Careful monitoring of patients who are taking medications that are affected by binding globulins is recommended.

5.13 Monitoring

Each wallet (28 tablets) contains the following:

- fumarate tablets do
- fumarate tablets for
- N21 on the other side
- fumarate tablets in
- N21 on the other side
- 24

5.14 Administration of COCs to Induce Withdrawal Bleeding

Use of COCs may worsen existing gallbladder disease. A past history of COC-related cholestasis should be considered when choosing a contraceptive method.

5.15 Use During Pregnancy

Use of COCs also increases the risk of thromboembolism, particularly deep vein thrombosis and pulmonary embolism, in women under the age of 35 years who smoke. If feasible, stop Blisovi 24 Fe at least 4 weeks before surgery and during the postoperative period. If bleeding persists or occurs after previously regular bleeding, consider the possibility of pregnancy. If pregnancy is confirmed, consider the possibility of continued use of Blisovi 24 Fe to reduce the risk of fetal harm.

5.17 Headache

Women with hypertriglyceridemia, or a family history thereof, may be at an increased risk of developing pancreatitis. Women with a history of gallbladder disease or pancreatic disease should be monitored for signs of exacerbation of their condition.

5.18 Use of COCs

Use of COCs during pregnancy is not indicated. Blisovi 24 Fe is contraindicated in women who are pregnant. If contraceptive failure occurs during pregnancy, administer the appropriate emergency contraceptive medication.

5.19 Oral Contraceptive Use for Prophylaxis Against Thromboembolism

5.21 Cerebrovascular Events and Stroke

5.22 Other Cardiovascular Events

5.23 Embolism

5.24 Other Cardiovascular Disorders

5.25 Use of COCs During Pregnancy

5.26 Use of COCs After Delivery

5.27 Use of COCs in Breastfeeding Women

5.28 Use of COCs During Menopause

5.29 Use of COCs in Women With a History of Thromboembolic Disease

5.30 Use of COCs in Women With a History of Liver Tumors

5.31 Use of COCs in Women With a History of Pancreatitis

5.32 Use of COCs in Women With a History of Porphyria

5.33 Use of COCs in Women With a History of Cholestasis

5.34 Use of COCs in Women With a History of Cholelithiasis

5.35 Use of COCs in Women With a History of Cholecystitis

5.36 Use of COCs in Women With a History of Carcinoma of the Breast

5.37 Use of COCs in Women With a History of Prostate Carcinoma

5.38 Use of COCs in Women With a History of Uterine Polyps

6.3 Pregnancy

6.4 Lactation

6.5 Premenstrual Syndrome

6.6 Amenorrhea

6.7 Menstrual Bleeding

6.8 Use During and After Pregnancy

6.9 Use During and After Delivery

6.10 Use in Postmenopausal Women

6.11 Use in Breastfeeding Women

6.12 Use in Women With a History of Thromboembolic Disease

6.13 Use in Women With a History of Liver Tumors

6.14 Use in Women With a History of Pancreatitis

6.15 Use in Women With a History of Porphyria

6.16 Use in Women With a History of Cholestasis

6.17 Use in Women With a History of Cholelithiasis

6.18 Use in Women With a History of Cholecystitis

6.19 Use in Women With a History of Carcinoma of the Breast

6.20 Use in Women With a History of Prostate Carcinoma

6.21 Use in Women With a History of Uterine Polyps

7.1 Pregnancy

7.2 Lactation

7.3 Premenstrual Syndrome

7.4 Amenorrhea

7.5 Menstrual Bleeding

7.6 Use During and After Pregnancy

7.7 Use During and After Delivery

7.8 Use in Postmenopausal Women

7.9 Use in Breastfeeding Women

7.10 Use in Women With a History of Thromboembolic Disease

7.11 Use in Women With a History of Liver Tumors

7.12 Use in Women With a History of Pancreatitis

7.13 Use in Women With a History of Porphyria

7.14 Use in Women With a History of Cholestasis

7.15 Use in Women With a History of Cholelithiasis

7.16 Use in Women With a History of Cholecystitis

7.17 Use in Women With a History of Carcinoma of the Breast

7.18 Use in Women With a History of Prostate Carcinoma

7.19 Use in Women With a History of Uterine Polyps

7.20 Use in Women With a History of Thromboembolic Disease

7.21 Use in Women With a History of Liver Tumors

7.22 Use in Women With a History of Pancreatitis

7.23 Use in Women With a History of Porphyria

7.24 Use in Women With a History of Cholestasis

7.25 Use in Women With a History of Cholelithiasis

7.26 Use in Women With a History of Cholecystitis

7.27 Use in Women With a History of Carcinoma of the Breast

7.28 Use in Women With a History of Prostate Carcinoma

7.29 Use in Women With a History of Uterine Polyps

8.1 Use During Subacute Bacterial Endocarditis

8.2 Use During and After Surgery

8.3 Use During and After Delivery

8.4 Use During and After Menopause

8.5 Use During and After Pregnancy

8.6 Use in Breastfeeding Women

8.7 Use in Women With a History of Thromboembolic Disease

8.8 Use in Women With a History of Liver Tumors

8.9 Use in Women With a History of Pancreatitis

8.10 Use in Women With a History of Porphyria

8.11 Use in Women With a History of Cholestasis

8.12 Use in Women With a History of Cholelithiasis

8.13 Use in Women With a History of Cholecystitis

8.14 Use in Women With a History of Carcinoma of the Breast

8.15 Use in Women With a History of Prostate Carcinoma

8.16 Use in Women With a History of Uterine Polyps

8.17 Use in Women With a History of Thromboembolic Disease

8.18 Use in Women With a History of Liver Tumors

8.19 Use in Women With a History of Pancreatitis

8.20 Use in Women With a History of Porphyria

8.21 Use in Women With a History of Cholestasis

8.22 Use in Women With a History of Cholelithiasis

8.23 Use in Women With a History of Cholecystitis

8.24 Use in Women With a History of Carcinoma of the Breast

8.25 Use in Women With a History of Prostate Carcinoma

8.26 Use in Women With a History of Uterine Polyps
No specific pharmacodynamic studies were conducted with Blisovi 24 Fe.

12.2 Pharmacodynamics
that reduce the likelihood of implantation. mechanisms may include cervical mucus changes that inhibit sperm penetration and endometrial changes COCs lower the risk of becoming pregnant primarily by suppressing ovulation. Other possible

12.1 Mechanism of Action

1 CLINICAL PHARMACOLOGY

The chemical name of norethindrone acetate is 17-hydroxy-19-nor-17α-pregn-4-en-20-yn-3-one, and the structural formula is:

The empirical formula of ethinyl estradiol is C18H20O2, and the structural formula is:

10 OVERDOSAGE

The pharmacokinetics of Blisovi 24 Fe has not been studied in women with renal impairment.

and WARNINGS AND PRECAUTIONS (3.5) of Blisovi 24 Fe does not contain ethinyl estradiol (EE) or norethindrone acetate (NEA).

Blisovi 24 Fe has not been studied in postmenopausal women and is not indicated in this population.

Safety and efficacy of Blisovi 24 Fe have been established in women of reproductive age. Efficacy is

8 USE IN SPECIFIC POPULATIONS

7 DRUG INTERACTIONS

The use of contraceptive steroids may influence the results of certain laboratory tests, such as

6.4 Reproductive System and Breast Disorders

Pollakiuria, dysuria, cystitis-like syndrome.

5.2 Effects on Other Drugs

The use of Blisovi 24 Fe has not been studied in women with renal impairment.

5.3 Effects on Laboratory Tests

The following adverse reactions have been identified during post approval use of Blisovi 24 Fe. (0.4%), increased blood pressure (0.4%), and irregular bleeding (0.4%).

The most common adverse reactions reported by at least 2% of the 743 women using Blisovi 24 Fe

Adverse Reactions Leading to Study Discontinuation

nausea (4.6%), menstrual cramps (4.4%), breast tenderness (3.4%), mood changes (including mood

The following adverse reactions are reported voluntarily from a population of uncertain size, it is difficult to

14 CLINICAL PHARMACOLOGY

For a normal dose of Blisovi 24 Fe tablets contains 1 mg norethindrone acetate and 20 mcg ethinyl estradiol. Inactive

5.12 Other Non-Hormonal Ingredients

5.11 Other Ingredients

5.10 Other Components

5.9 Carbohydrate (Sugars, Starches)

5.8 Excipients

5.7 Water

5.6 Pigments

5.5 Lactose

5.4 Sodium Starch Glycolate

5.3 Mannitol

5.2 Sodium Carboxymethylcellulose

5.1 Sodium Polymethacrylate

4.1 Pregnancy

4.3 Nursing Mothers

4.2 Lactation

4.1 Pregnancy

4.1 Pregnancy

4.0 Contraception

3.6 Mutagenicity

3.5 Teratogenicity

3.4 Local Toxicity

3.3 Subchronic Toxicity

3.2 Reproduction

3.1 Other contraceptive methods are more effective and reduce the risk of sexually transmitted infections and diseases.

3.0 INDICATIONS AND USAGE

2.3 General Information

2.2 Clinical Pharmacology

2.1 Mechanism of Action

1 Mechanism of Action

COCs block the release of gonadotropin by the pituitary gland. Other possible

1.5 Pharmacodynamics

No specific pharmacodynamic studies were conducted with Blisovi 24 Fe.

1.4 Mechanism of Action

COCs block the release of gonadotropin by the pituitary gland. Other possible

1.2 Mechanism of Action

COCs block the release of gonadotropin by the pituitary gland. Other possible

1.1 Mechanism of Action

COCs block the release of gonadotropin by the pituitary gland. Other possible
Each wallet (28 tablets) contains in the following order:

(NDC 68180-864-11). Such three pouches are packaged in a carton (NDC 68180-864-13).

Blisovi 24 Fe is available in a wallet (NDC 68180-864-11) containing 28 tablets packed in a pouch

16.1 How Supplied

The plasma norethindrone and ethinyl estradiol pharmacokinetics following single- and multiple-dose administrations of Blisovi 24 Fe tablets in 17 healthy female volunteers are provided in

Table 1. Summary of Observations (N = 17) and Derived Parameters Following Single- and Multiple-Dose Administration of Blisovi 24 Fe Tablets in Healthy Female Volunteers Under Fasting Conditions (n = 17)

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Single Dose Administration</th>
<th>Multiple Dose Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norethindrone</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tmax (hr)</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Cmax (ng/mL)</td>
<td>8.3</td>
<td>6.0</td>
</tr>
<tr>
<td>Cavg (ng/mL)</td>
<td>4.6</td>
<td>3.1</td>
</tr>
<tr>
<td>Ethinyl Estradiol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tmax (hr)</td>
<td>1.3</td>
<td>1.3</td>
</tr>
<tr>
<td>Cmax (ng/mL)</td>
<td>1.3</td>
<td>1.3</td>
</tr>
<tr>
<td>Cavg (ng/mL)</td>
<td>1.3</td>
<td>1.3</td>
</tr>
</tbody>
</table>

The plasma norethindrone and ethinyl estradiol pharmacokinetics following single- and multiple-dose administrations of Blisovi 24 Fe tablets in 17 healthy female volunteers are provided in

Table 1. Summary of Observations (N = 17) and Derived Parameters Following Single- and Multiple-Dose Administration of Blisovi 24 Fe Tablets in Healthy Female Volunteers Under Fasting Conditions (n = 17)

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Single Dose Administration</th>
<th>Multiple Dose Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norethindrone</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tmax (hr)</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Cmax (ng/mL)</td>
<td>8.3</td>
<td>6.0</td>
</tr>
<tr>
<td>Cavg (ng/mL)</td>
<td>4.6</td>
<td>3.1</td>
</tr>
<tr>
<td>Ethinyl Estradiol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tmax (hr)</td>
<td>1.3</td>
<td>1.3</td>
</tr>
<tr>
<td>Cmax (ng/mL)</td>
<td>1.3</td>
<td>1.3</td>
</tr>
<tr>
<td>Cavg (ng/mL)</td>
<td>1.3</td>
<td>1.3</td>
</tr>
</tbody>
</table>

The plasma norethindrone and ethinyl estradiol pharmacokinetics following single- and multiple-dose administrations of Blisovi 24 Fe tablets in 17 healthy female volunteers are provided in

Table 1. Summary of Observations (N = 17) and Derived Parameters Following Single- and Multiple-Dose Administration of Blisovi 24 Fe Tablets in Healthy Female Volunteers Under Fasting Conditions (n = 17)

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Single Dose Administration</th>
<th>Multiple Dose Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norethindrone</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tmax (hr)</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Cmax (ng/mL)</td>
<td>8.3</td>
<td>6.0</td>
</tr>
<tr>
<td>Cavg (ng/mL)</td>
<td>4.6</td>
<td>3.1</td>
</tr>
<tr>
<td>Ethinyl Estradiol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tmax (hr)</td>
<td>1.3</td>
<td>1.3</td>
</tr>
<tr>
<td>Cmax (ng/mL)</td>
<td>1.3</td>
<td>1.3</td>
</tr>
<tr>
<td>Cavg (ng/mL)</td>
<td>1.3</td>
<td>1.3</td>
</tr>
</tbody>
</table>
Important Information about taking Blisovi 24 Fe

Blisovi 24 Fe is a combined oral contraceptive tablet that contains two active ingredients: norethindrone acetate and ethinyl estradiol, along with ferrous fumarate. This medication is used by women to prevent pregnancy.

*INSTRUCTIONS FOR USE*

**Brown pills:** ferrous fumarate

**Inactive ingredients:**

**Active ingredients:**

- Norethindrone acetate
- Ethinyl estradiol
- Ferrous fumarate

**What are the ingredients in Blisovi 24 Fe?**

Your periods may be lighter and shorter than usual. Some women may miss a period. Irregular vaginal bleeding may occur. You may need to use an alternative form of contraception (such as condoms and spermicide) during this time period.

**How should I store Blisovi 24 Fe?**

- Keep Blisovi 24 Fe and all medicines out of the reach of children.
- Store away from heat.

**What else should I know about taking Blisovi 24 Fe?**

You may report side effects to the FDA at 1-800-FDA-1088.

**Provider or pharmacist.**

**What are the most common side effects of Blisovi 24 Fe?**

- Mood changes
- Headaches
- Nausea
- Breast tenderness
- Swelling in the feet, legs, or hands
- Weight gain

There are also less common side effects of Blisovi 24 Fe. For more information, ask your healthcare provider.

**Who should not take Blisovi 24 Fe?**

- Women who are pregnant
- Women who are breast feeding or plan to breast feed
- Women who are allergic to any ingredients of Blisovi 24 Fe
- Women who have certain medical conditions
- Women who smoke
- Women who have certain blood clots

**Who should talk to their healthcare provider before using Blisovi 24 Fe?**

- Women who have or have had blood clots
- Women who have had a stroke
- Women who have had a heart attack
- Women who have had a problem with blood clots
- Women who have a history of high blood pressure
- Women who have had a history of diabetes
- Women who smoke
- Women who have any cancer

**Tell your healthcare provider if you:**

- Have had a blood clot in your legs, lungs, heart, or brain
- Have had a stroke or heart attack
- Have high blood pressure
- Have diabetes
- Have a history of problems with blood clots
- Have a history of high blood pressure
- Have high cholesterol
- Have ever been diagnosed with diabetes
- Have an enlarged breast
- Have diabetes
- Have high blood pressure
- Have a history of diabetes
- Have a history of high blood pressure
- Have a history of heart disease
- Have a history of high cholesterol
- Have a history of blood clots

**What is Blisovi 24 Fe?**

Blisovi 24 Fe is a birth control pill (hormonal contraceptive) used by women to prevent pregnancy.

**What is Blisovi 24 Fe used for?**

- Blisovi 24 Fe is used to prevent pregnancy.
- Blisovi 24 Fe is also used to treat acne in women who have severe acne.

**How does Blisovi 24 Fe work for contraception?**

Blisovi 24 Fe works by preventing ovulation (the release of an egg from the ovary) and thickening the cervical mucus to make it more difficult for sperm to pass through the cervix. Blisovi 24 Fe also thins the lining of the uterus, making it less likely for a fertilized egg to implant.

**How do I take Blisovi 24 Fe?**

Take Blisovi 24 Fe every day at the same or different birth control pills after not using them for a month

**Who should take Blisovi 24 Fe?**

- Women
- Women with acne
- Women who need estrogen therapy

**When should I take Blisovi 24 Fe?**

- Every day at the same time
- On the same day each week

**When should I not take Blisovi 24 Fe?**

- If you are pregnant
- If you are breast feeding
- If you have certain medical conditions
- If you smoke
- If you have certain blood clots

**What should I do if I miss a pill?**

- Do not take 2 pills at the same time.
- Take the missed pill as soon as you remember it. For example, if you take your pill at 3 PM, then take your next pill at 3 PM on the next day.
- If you miss a pill during the first 3 days of the pack, you are still protected against pregnancy.
- If you miss a pill during the last 3 days of the pack, you may not be protected against pregnancy. Take the missed pill as soon as you remember it. Then, continue to take your pills for the rest of the pack.

**What if I am late taking Blisovi 24 Fe?**

- If you are late taking Blisovi 24 Fe, you may not be protected against pregnancy. Take the missed pill as soon as you remember it. Then, continue to take your pills for the rest of the pack.

**What if I am vomiting or diarrhea?**

- If you vomit or diarrhea within 4 hours of taking a pill, you do not have to use additional birth control during this time period.
- If you vomit or diarrhea after 4 hours of taking a pill, you may not be protected against pregnancy. Take the missed pill as soon as you remember it. Then, continue to take your pills for the rest of the pack.

**What if I have nausea or vomiting?**

- If you have nausea or vomiting, you should stop taking Blisovi 24 Fe. If you vomit or diarrhea after 4 hours of taking a pill, you may not be protected against pregnancy. Take the missed pill as soon as you remember it. Then, continue to take your pills for the rest of the pack.

**What if I have diarrhea?**

- If you have diarrhea, you should stop taking Blisovi 24 Fe. If you vomit or diarrhea after 4 hours of taking a pill, you may not be protected against pregnancy. Take the missed pill as soon as you remember it. Then, continue to take your pills for the rest of the pack.

**What if I am late taking Blisovi 24 Fe?**

- If you are late taking Blisovi 24 Fe, you should stop taking Blisovi 24 Fe. If you vomit or diarrhea after 4 hours of taking a pill, you may not be protected against pregnancy. Take the missed pill as soon as you remember it. Then, continue to take your pills for the rest of the pack.

**What should I do if I get pregnant?**

- If you get pregnant while taking Blisovi 24 Fe, you should stop taking Blisovi 24 Fe. If you vomit or diarrhea after 4 hours of taking a pill, you may not be protected against pregnancy. Take the missed pill as soon as you remember it. Then, continue to take your pills for the rest of the pack.

**What if I have problems with Blisovi 24 Fe?**

- If you have problems with Blisovi 24 Fe, you should stop taking Blisovi 24 Fe. If you vomit or diarrhea after 4 hours of taking a pill, you may not be protected against pregnancy. Take the missed pill as soon as you remember it. Then, continue to take your pills for the rest of the pack.

**What if I have problems with Blisovi 24 Fe?**

- If you have problems with Blisovi 24 Fe, you should stop taking Blisovi 24 Fe. If you vomit or diarrhea after 4 hours of taking a pill, you may not be protected against pregnancy. Take the missed pill as soon as you remember it. Then, continue to take your pills for the rest of the pack.
Blisovi™ 24 Fe \[norethindrone acetate and ethinyl estradiol tablets USP, (1 mg/0.02 mg) and ferrous fumarate tablets, (75 mg)]

Pouch Label: 1 wallet of 28 Tablets

NDC 68180-864-11

Rx only

Administration.

This Patient Information and Instructions for Use has been approved by the U.S. Food and Drug Administration.

INDIA

Lupin Limited

Manufactured by:

United States

Baltimore, Maryland 21202

Lupin Pharmaceuticals, Inc.

Distributed by:

Blisovi

provider.

If you have any questions or are unsure about the information in this leaflet, call your healthcare provider.

If you miss any of the 4 brown "reminder" pills in Week 4 and you are taking Blisovi 24 Fe as a single pill contraceptive method, do not use a back-up method of birth control. If you are using Blisovi 24 Fe as a combination contraceptive method in any 30-day cycle, use a non-hormonal back-up method if you have sex during the first 7 days after you restart your pills.

Keep taking 1 pill every day until you finish the pack. You do not need to use a back-up method of birth control if you have sex during the first 7 days after missing your pills during the first 30 days of the cycle when you are taking Blisovi 24 Fe as a single pill contraceptive method. If you are using Blisovi 24 Fe as a combination contraceptive method in any 30-day cycle, use a non-hormonal back-up method if you have sex during the first 7 days after missing your pills during the first 30 days of the cycle.

If you miss 2 white pills in a row in Week 1 or Week 2, or you miss 3 or more white pills in a row in Week 3 or Week 4, follow these steps:

First, find your Figure. Take the first pill you missed at your regular time. Take the next pill at your regular time. Take the next pill the next day. Take the fourth pill the next day.

If you start taking Blisovi 24 Fe and you are switching from an intrauterine device or system (IUD or IUS):

Start using Blisovi 24 Fe on the day you would have reapplied the IUD or IUS.

If you start taking Blisovi 24 Fe and you are switching from a progestin-only method such as an implant or injection:

Start using Blisovi 24 Fe at any time after the dose of your previous method.

If you start taking Blisovi 24 Fe and you are switching from a combination contraceptive method:

Start using Blisovi 24 Fe as soon as you remember. Take the first pill that you missed at your regular time. Take the next pill at your regular time. Continue to take 1 pill every day until you finish the pack.

If you start taking Blisovi 24 Fe and you have not used a hormonal birth control method before:

Start using Blisovi 24 Fe on the day you would have started your new birth control method.

When should I start taking Blisovi 24 Fe?

There are 2 ways to start using Blisovi 24 Fe:

- Day 1 Start
- Sunday Start

You will use a calendar that shows day 1 of each week to track when you start taking your pack.

If this is the first time you are using Blisovi 24 Fe:

If you start taking Blisovi 24 Fe and you are switching from an intrauterine device or system (IUD or IUS):

Start using Blisovi 24 Fe on the day you would have reapplied the IUD or IUS.

If you start taking Blisovi 24 Fe and you are switching from a progestin-only method such as an implant or injection:

Start using Blisovi 24 Fe at any time after the dose of your previous method.

If you start taking Blisovi 24 Fe and you are switching from a combination contraceptive method:

Start using Blisovi 24 Fe as soon as you remember. Take the first pill that you missed at your regular time. Take the next pill at your regular time. Continue to take 1 pill every day until you finish the pack.

If you start taking Blisovi 24 Fe and you have not used a hormonal birth control method before:

Start using Blisovi 24 Fe on the day you would have started your new birth control method.

When should I start taking Blisovi 24 Fe?
**Lupin Pharmaceuticals, Inc.**

**NDC 68180-864-13**

**Carton Label:** 3 wallets of 28 Tablets

**BLISOVI 24 FE**

**norethindrone acetate and ethinyl estradiol kit**

**Product Information**

**Product Type:** HUMAN PRESCRIPTION DRUG

**Item Code (Source):** NDC:68180-864

**Packaging**

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:68180-864-13</td>
<td>3 in 1 CARTON</td>
<td>01/14/2016</td>
<td>12/31/2020</td>
</tr>
</tbody>
</table>

**Quantity of Parts**

<table>
<thead>
<tr>
<th>Part</th>
<th>#</th>
<th>Package Quantity</th>
<th>Total Product Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>24</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Route of Administration:** ORAL

**Active Ingredient/Active Moiety**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>ETHINYL ESTRADIOL</td>
<td>(ETHINYL ESTRADIOL - UNII:423D2T571U)</td>
<td>0.02 mg</td>
</tr>
<tr>
<td>NORETINDRONE ACETATE</td>
<td>(NORETHINDRONE - UNII:T18F433X4S)</td>
<td>1 mg</td>
</tr>
</tbody>
</table>

**Inactive Ingredients**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACACIA</td>
<td></td>
</tr>
<tr>
<td>LACTOSE MONOHYDRATE</td>
<td></td>
</tr>
<tr>
<td>MAGNESIUM STEARATE</td>
<td></td>
</tr>
<tr>
<td>STARCH, CORN</td>
<td></td>
</tr>
<tr>
<td>SUCROSE</td>
<td></td>
</tr>
<tr>
<td>TALC</td>
<td></td>
</tr>
</tbody>
</table>

**Product Characteristics**

<table>
<thead>
<tr>
<th>Color</th>
<th>Score</th>
<th>Shape</th>
<th>Size</th>
<th>Flavor</th>
<th>Imprint Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHITE (white to off white)</td>
<td>no score</td>
<td>ROUND (round; flat face beveled edge)</td>
<td>6mm</td>
<td>Imprint Code</td>
<td></td>
</tr>
</tbody>
</table>

**Marketing Information**

**Marketing Category:** ANDA

**Application Number or Monograph Citation:** ANDA091398

**Marketing Start Date:** 01/14/2016
**Marketing End Date:** 12/31/2020

**Labeler:** Lupin Pharmaceuticals, Inc. (089153071)

**Registrant:** LUPIN LIMITED (675923163)

**Establishment**

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
</tr>
</thead>
<tbody>
<tr>
<td>LUPIN LIMITED</td>
<td></td>
<td>650582310</td>
</tr>
</tbody>
</table>

**Contents:**

- Norethindrone Acetate
- Ethinyl Estradiol

**Marketing Information**

**Marketing Category:** ANDA

**Application Number or Monograph Citation:** ANDA091398

**Marketing Start Date:** 01/14/2016
**Marketing End Date:** 12/31/2020

**Labeler:** Lupin Pharmaceuticals, Inc. (089153071)

**Registrant:** LUPIN LIMITED (675923163)

**Establishment**

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
</tr>
</thead>
<tbody>
<tr>
<td>LUPIN LIMITED</td>
<td></td>
<td>650582310</td>
</tr>
</tbody>
</table>

**Contents:**

- Norethindrone Acetate
- Ethinyl Estradiol

**Marketing Information**

**Marketing Category:** ANDA

**Application Number or Monograph Citation:** ANDA091398

**Marketing Start Date:** 01/14/2016
**Marketing End Date:** 12/31/2020

**Labeler:** Lupin Pharmaceuticals, Inc. (089153071)

**Registrant:** LUPIN LIMITED (675923163)

**Establishment**

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
</tr>
</thead>
<tbody>
<tr>
<td>LUPIN LIMITED</td>
<td></td>
<td>650582310</td>
</tr>
</tbody>
</table>

**Contents:**

- Norethindrone Acetate
- Ethinyl Estradiol

**Marketing Information**

**Marketing Category:** ANDA

**Application Number or Monograph Citation:** ANDA091398

**Marketing Start Date:** 01/14/2016
**Marketing End Date:** 12/31/2020

**Labeler:** Lupin Pharmaceuticals, Inc. (089153071)

**Registrant:** LUPIN LIMITED (675923163)

**Establishment**

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
</tr>
</thead>
<tbody>
<tr>
<td>LUPIN LIMITED</td>
<td></td>
<td>650582310</td>
</tr>
</tbody>
</table>