First-trimester:
Starting Norgestimate and Ethinyl Estradiol Tablets USP after Abortion or Miscarriage.

Potential to prevent pregnancy with enzyme induction.

**1.1 Oral Contraceptive**

- Tablet
- Important
- Starting

---

**2.2 Instructions for Use**

- On the day of removal
- Take first active tablet without regard to meals on the first Sunday after the onset of menses.
- Take one green inactive tablet daily for the following 7 days and at the same time of day that active tablets were taken.

---

**8.4 Carbohydrate and Lipid Metabolic Effects**

- If used in women with diabetes mellitus, baseline blood glucose levels should be monitored.

---

**14.1 Contraception**

- Co-administration with or without
- In women who are
- Additional non-hormonal contraception (such as
- Additional non-hormonal contraception (such as
- Additional non-hormonal contraception (such as
- Additional non-hormonal contraception (such as
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**Table 1**

<table>
<thead>
<tr>
<th>Dosage Forms and Strengths</th>
<th>Administered Cheek Pocket Device USP</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.25 mg Norgestimate and 0.03 mg Ethinyl Estradiol Tablets USP</td>
<td>For Women Currently Using a Hormonal Contraceptive</td>
</tr>
<tr>
<td>0.5 mg Norgestimate and 0.06 mg Ethinyl Estradiol Tablets USP</td>
<td>For Women Not Currently Using a Hormonal Contraceptive</td>
</tr>
</tbody>
</table>

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**2.4 Advice in Case of Gastrointestinal Disturbances**

- Do not skip or delay tablet intake.
- Take tablets in the order directed on the wallet.
If missed period and take appropriate diagnostic measures. If the patient has adhered to the prescribed medication, consider the possibility of pregnancy at the time of the first follow-up visit. If scheduled (withdrawal) bleeding does not occur, consider the possibility of pregnancy. If the patient has had a normal period, re-check her date of last menstrual period. If pathology and pregnancy are excluded, bleeding tends to decrease over time.

Table 2: Instructions for Missed Norgestimate and Ethinyl Estradiol Tablets

<table>
<thead>
<tr>
<th>Instructions</th>
<th>Course of action</th>
</tr>
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<tbody>
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<td>Take 2 missed tablets as soon as possible and the next 2 active tablets on the next day. Take the next 2 tablets at the usual time. Continue taking one tablet a day until the pack is finished.</td>
</tr>
</tbody>
</table>

5.3 Nausea

Nausea is a common side effect of COCs. It usually resolves within the first 3 months of use. If nausea is severe or persistent, consider using an alternative contraceptive method or reducing the dose of the progestin component in the COC.

5.4 High Blood Pressure

Women who use norgestimate and ethinyl estradiol tablets may experience amenorrhea. Some women will have adverse lipid changes while on COCs. Carefully monitor prediabetic and diabetic women who take norgestimate and ethinyl estradiol tablets.

5.5 Impaired Liver Function

5.6 Carbohydrate and Lipid Metabolic Effects

Studies suggest a small increased relative risk of developing gallbladder disease among COC users. Discontinue norgestimate and ethinyl estradiol tablets if jaundice develops.

5.7 Impaired Fertility

5.8 Breast Changes

5.9 Nongynecologic or Other Adverse Reactions

5.10 Use in Pregnancy

5.11 Use in Lactation

5.12 Use in Patients with Renal Impairment

5.13 Use in Pediatric Patients

5.14 Use in Elderly Patients

5.15 Use in Women of Childbearing Potential

5.16 Use in Men

5.17 Drug Interactions

5.18 Overdose

5.19 Hepatic Impairment

5.20 Pregnancy

5.21 Contraceptive Efficacy

5.22 Summary of Clinical Studies

6.7 Missed Tablets

7.2 Stable or Coarse Disturbances

7.3 Impaired Liver Function

7.4 Nongynecologic or Other Adverse Reactions

7.5 Use in Pregnancy

7.6 Use in Lactation

7.7 Overdose

7.8 Hepatic Impairment

7.9 Pregnancy

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8.2 Stable or Coarse Disturbances

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8.5 Use in Pregnancy

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8.11 Summary of Clinical Studies

9.2 Stable or Coarse Disturbances

9.3 Impaired Liver Function

9.4 Nongynecologic or Other Adverse Reactions

9.5 Use in Pregnancy

9.6 Use in Lactation

9.7 Overdose

9.8 Hepatic Impairment

9.9 Pregnancy

9.10 Contraceptive Efficacy

9.11 Summary of Clinical Studies

10.2 Stable or Coarse Disturbances

10.3 Impaired Liver Function

10.4 Nongynecologic or Other Adverse Reactions

10.5 Use in Pregnancy

10.6 Use in Lactation

10.7 Overdose

10.8 Hepatic Impairment

Table 3: Instructions for Missed Norgestimate and Ethinyl Estradiol Tablets

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</table>
5.13 Monitoring
A woman who is taking COCs should have a yearly visit with her healthcare provider for a blood test to check for or confirm liver function abnormalities.

5.14 Hereditary Angioedema
In women with hereditary angioedema, exogenous estrogens may induce or exacerbate symptoms of angioedema.

5.15 Chloasma
In women with melasma, use of COCs may increase the size, number, or severity of lesions.

5.16 Pregnancy
Use of COCs is not effective immediately following placement of an intrauterine device (IUD) or intrauterine contraceptive device (IUD)撤除, or following a menstrual period. In women who have not used hormonal contraceptives, or have used other methods of contraception, the first active pill within the first 5 days after the onset of menses should be started. In women who have used hormonal contraceptives, the first active pill within the first 5 days after the onset of menses should be started on the same day. Use of COCs in women older than 35 years is not recommended.

6.1 Precautions
6.1.1 Pregnancy
The use of COCs should be discontinued immediately if pregnancy is confirmed. Women who continue to use COCs after pregnancy are at increased risk of severe complications, including pulmonary embolism and arterial thromboembolism.

6.2 Postmarketing Experience
Serious adverse drug reactions have been reported following the use of COCs. See the labeling of concurrently used drugs to obtain further information about interactions with other drugs.

6.3 Medication Guide
A Medication Guide should accompany each prescription of this product. See the labeling of concurrently used drugs to obtain further information about interactions with other drugs.

7.1 Effects of Other Drugs on Combined Oral Contraceptives
Drugs or herbal products that induce certain enzymes, including cytochrome P450 3A4 (CYP3A4), may increase the plasma concentrations of COCs and poten...
Norgestimate and Ethinyl Estradiol Tablets

Norgestimate and Ethinyl Estradiol Tablets are intended for oral administration and contain norgestimate and ethinyl estradiol. The tablets are intended to provide anticonception and hormone replacement therapy at low doses of norgestimate and ethinyl estradiol, respectively.

**Pharmacokinetics**

Norgestimate (NGM) and EE are rapidly absorbed following oral administration. NGM is extensively metabolized by first-pass mechanisms in the gastrointestinal tract and/or liver. NGM is metabolized primarily to NGMN, which is further metabolized to norelgestromin (NGMN). Other metabolites include 17-deacetyl norgestimate, 17α-norgestimate, and 13-ethyl-17α-norgestimate.

EE is also rapidly absorbed following oral administration. It is conjugated with sulfate and glucuronide, and a small amount is metabolized to estrone (EE-1). The major metabolites are estrone sulfate and estradiol-3-glucuronide.

**Pharmacodynamics**

The pharmacodynamics of norgestimate and ethinyl estradiol tablets have not been studied in specific populations such as African-American, nonwhite, Asian or Other (≤1%). There were no exclusions on the basis of weight; the weight range was about 73 to 86% Caucasian, 8 to 13% African-American, 6 to 14% Hispanic with the remainder Asian or Other (≤1%). There were no exclusions on the basis of weight; the weight range was about 73 to 86% Caucasian, 8 to 13% African-American, 6 to 14% Hispanic with the remainder Asian or Other (≤1%).

**Clinical Studies**

[see WARNINGS AND PRECAUTIONS (13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility)]

**Nonclinical Toxicology**

[see NONCLINICAL TOXICOLOGY (13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility)]

**DOSAGE AND ADMINISTRATION**

Norgestimate and ethinyl estradiol tablets are not to be used by women who are pregnant, breastfeeding, or have had a hysterectomy.

**Contraindications**

[see CONTRAINDICATIONS (5.11 Pregnancy (including breastfeeding))]
What should I know about my period when taking norgestimate and ethinyl estradiol tablets?

What are the possible side effects of norgestimate and ethinyl estradiol tablets?

What are the possible serious side effects of norgestimate and ethinyl estradiol tablets?

How should I store norgestimate and ethinyl estradiol tablets?

How should I use norgestimate and ethinyl estradiol tablets?

Do not use norgestimate and ethinyl estradiol tablets for a condition for which it was not prescribed. Do not give norgestimate and ethinyl estradiol tablets to other people, even if they have the same symptoms that you have. It may harm them even if their symptoms are the same as yours.

What are the precautions regarding the use of norgestimate and ethinyl estradiol tablets?

What is the most important information I should know about norgestimate and ethinyl estradiol tablets?

You may return to your healthcare provider and pharmacist and ask about the medicines you take. You can ask about the medicines you take and about the effects of medicines on your health and on other medicines you take.

Norgestimate and ethinyl estradiol tablets may affect the way other medicines work, and other medicines may affect the way norgestimate and ethinyl estradiol tablets work.

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You should see your healthcare provider for a yearly check of your blood pressure and a Pap test for cervical cancer.

You should not take norgestimate and ethinyl estradiol tablets with other medications that contain hormones, such as estrogen or progesteron.

What are norgestimate and ethinyl estradiol tablets?

These tablets are available as light blue, round tablets. Each tablet contains norgestimate and ethinyl estradiol. Each tablet also contains the following inactive ingredients:

What are norgestimate and ethinyl estradiol tablets useful for contraception?

What should I tell my healthcare provider before taking norgestimate and ethinyl estradiol tablets?

What are norgestimate and ethinyl estradiol tablets?

Norgestimate and ethinyl estradiol tablets are available as light blue, round tablets. Each tablet contains norgestimate and ethinyl estradiol. Each tablet also contains the following inactive ingredients:

What should I tell my healthcare provider before taking norgestimate and ethinyl estradiol tablets?

A small amount of the hormones in norgestimate and ethinyl estradiol tablets may be released into your breast milk. It is not known if these hormones will affect your baby. Call your healthcare provider if you are planning to breast feed and you are taking norgestimate and ethinyl estradiol tablets.

What are the possible side effects of norgestimate and ethinyl estradiol tablets?

What are the precautions regarding the use of norgestimate and ethinyl estradiol tablets?

What are the precautions regarding the use of norgestimate and ethinyl estradiol tablets?

What should I tell my healthcare provider before taking norgestimate and ethinyl estradiol tablets?

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What are the possible side effects of norgestimate and ethinyl estradiol tablets?
Norgestimate and Ethinyl Estradiol Tablets

For all intents and purposes, this document contains important information about the correct usage of norgestimate and ethinyl estradiol tablets. It is crucial to read and follow these instructions carefully to ensure proper use of the medication.

Before you start taking norgestimate and ethinyl estradiol tablets:
- **Be sure to read the instructions below for taking your birth control pills.**
- **Do not miss any pills.**
- **Do not change your method of contraception.**

**What should I do if I miss any norgestimate and ethinyl estradiol tablets?**

If you miss 2 pills in a row in Week 3, or you miss 3 or more pills in a row during Weeks 1, 2, or 3 of the pack, follow these steps:
- Step 1. Take the first missed pill immediately. Take the second missed pill at your regular time. This means you may double up on the day you missed the pill(s).
- Step 2. Take your pill at the same time every day.
- Step 3. Take the rest of your pills as usual.

If you miss 1 pill in Weeks 1, 2, or 3, follow these steps:
- Step 1. Take the missed pill now. Take your next pill at your regular time.
- Step 2. Take your pill at the same time every day.
- Step 3. Take the rest of your pills as usual.

**What should I do if I have sex during the first 7 days after you restart your pills?**

- If you have sex during the first 7 days after you restart your pills, you are having your period. You do not need back-up contraception if your IUD or IUS is still in place. Call your healthcare provider if this does not happen. If you have sex during the first 7 days after you restart your pills, you could become pregnant if you have sex during the first 7 days after you restart your pills.

**What should I do if I am pregnant or think I might be pregnant?**

- If you think you might be pregnant or if you are already pregnant, you must contact your healthcare provider immediately. Call your healthcare provider if you have sex during the first 7 days after you restart your pills.

**What should I do if I think my birth control method might have failed?**

- If you think your birth control method might have failed, you must contact your healthcare provider immediately. Call your healthcare provider if you have sex during the first 7 days after you restart your pills.

**What should I do if I am taking medication that affects my liver?**

- If you are taking medication that affects your liver, you must contact your healthcare provider immediately. Call your healthcare provider if you have sex during the first 7 days after you restart your pills.

**What should I do if I am taking other medications that might affect my liver?**

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Norgestimate and Ethinyl Estradiol Tablets USP
Rx Only
NDC 68180-840-11

Wallet Label: 28 Tablets
Pouch Label: 28 Tablets
Carton Label: 3 wallets of 28 Tablets each

NORGESTIMATE AND ETHINYL ESTRADIOL
norgestimate and ethinyl estradiol
tablet, film coated

Product Information

Route of Administration
ORAL

Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td>ETHINYL ESTRADIOL</td>
<td>(ETHINYL ESTRADIOL - UNII:423D2T571U)</td>
<td>0.035 mg</td>
</tr>
<tr>
<td>NORGESTIMATE</td>
<td>(NORGESTIMATE - UNII:C291HFX4DY)</td>
<td>0.25 mg</td>
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</table>

Inactive Ingredients

<table>
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</tr>
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<tbody>
<tr>
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<td></td>
</tr>
<tr>
<td>ANHYDROUS LACTOSE</td>
<td></td>
</tr>
<tr>
<td>CELLULOSE, MICROCRYSTALLINE</td>
<td></td>
</tr>
<tr>
<td>CROSCARMELLOSE SODIUM</td>
<td></td>
</tr>
<tr>
<td>FD&amp;C BLUE NO. 2</td>
<td></td>
</tr>
<tr>
<td>HYPROMELLOSE 2910 (6 MPA.S)</td>
<td></td>
</tr>
<tr>
<td>LACTOSE MONOHYDRATE</td>
<td></td>
</tr>
<tr>
<td>MAGNESIUM STEARATE</td>
<td></td>
</tr>
<tr>
<td>POLYETHYLENE GLYCOL 400</td>
<td></td>
</tr>
<tr>
<td>POVIDONES</td>
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<tr>
<td>TITANIUM DIOXIDE</td>
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Product Characteristics

Color: BLUE
Score: no score
Shape: ROUND
Size: 5mm
Flavor: Imprint Code: LU;E27

Contains:

Marketing Information

Marketing Category
ANDA
Application Number or Monograph Citation
ANDA205630
Marketing Start Date
01/23/2017
Marketing End Date
01/23/2017

Part 2 of 2
INERT
inert
tablet, film coated

Product Information

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ORAL
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<tr>
<td>CROSCARMELLOSE SODIUM</td>
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</tr>
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<td>FD&amp;C BLUE NO. 2</td>
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<td>FERRIC OXIDE YELLOW</td>
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<tr>
<td>TITANIUM DIOXIDE</td>
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</table>

**Product Characteristics**

- **Color**: GREEN
- **Score**: no score
- **Shape**: ROUND (biconvex)
- **Size**: 5mm
- **Flavor**: Imprint Code: E24; LU

**Marketing Information**

- **Marketing Category**: ANDA
- **Application Number or Monograph Citation**: ANDA205630
- **Marketing Start Date**: 01/23/2017
- **Marketing End Date**: 

**Labeler**

- **Labeler**: Lupin Pharmaceuticals, Inc.
- **Registrant**: LUPIN LIMITED (675923163)

**Establishment**

- **Establishment Name**: LUPIN LIMITED
- **Establishment Address**: 650582310
- **Establishment ID/FEI**: MANUFACTURE(68180-840), PACK(68180-840)

**Revised**: 12/2017