Hormonal contraception (such as condoms and spermicide) for the first seven days of the patient’s first menstrual cycle is recommended. (See CLINICAL STUDIES (4).)

If norgestimate and ethinyl estradiol tablets USP is not started within 5 days after termination of the contraceptive method being used, the patient should use additional non-hormonal contraception (such as condoms and spermicide) for the first seven days of the patient’s first menstrual cycle. (See CLINICAL STUDIES (4)).

2.2 How to Take Norgestimate and Ethinyl Estradiol Tablets USP

Norgestimate and ethinyl estradiol tablets USP are dispensed in a blister. Norgestimate and ethinyl estradiol tablets USP are active tablets white (Day 1 to Day 7), light blue (Day 8 to Day 15) and blue (Day 16 to Day 21).

Norgestimate and ethinyl estradiol tablets USP should be used as directed by the healthcare provider. Take subsequent active tablets once daily at the same time each day for a total of 21 days. (See CLINICAL STUDIES (4)).

If the IUD is not removed on first day of the patient’s menstrual cycle, additional non-hormonal contraception (such as condoms and spermicide) for the first seven days of the patient’s first menstrual cycle is recommended. (See CLINICAL STUDIES (4)).

If the IUD is not removed on first day of the patient’s menstrual cycle, additional non-hormonal contraception (such as condoms and spermicide) for the first seven days of the patient’s first menstrual cycle is recommended. (See CLINICAL STUDIES (4)).

2.4 Advice in Case of Gastrointestinal Disturbances

Gastrointestinal disturbances such as nausea, vomit, and diarrhea may be related to COC use. COC users may be more susceptible to these disturbances because COCs decrease the motility of gastrointestinal cells, including the small intestine. Nausea may be alleviated by taking the tablets after meals or at bedtime. (See CLINICAL STUDIES (4)).

2.3 Missed Tablets

Intrauterine contraceptive devices (IUDs) have been demonstrated to be more effective than the COCs. (See CLINICAL STUDIES (4)).

Table 1: Instructions for Administration of Norgestimate and Ethinyl Estradiol Tablets USP

<table>
<thead>
<tr>
<th>Dosage</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>21-day pack</td>
<td>Take 21 active tablets, one daily, for 21 days. (See CLINICAL STUDIES (4)).</td>
</tr>
<tr>
<td>7-day pack</td>
<td></td>
</tr>
</tbody>
</table>

3.1 Contraindications

Norgestimate and ethinyl estradiol tablets USP are contraindicated in women over 35 years old who smoke. (See CLINICAL STUDIES (4)).

3.2 Warnings

Norgestimate and ethinyl estradiol tablets USP are contraindicated in women with uncontrolled dyslipidemia. (See CLINICAL STUDIES (4)).

4.1 Pregnancy

Norgestimate and ethinyl estradiol tablets USP are estrogen/progestin COCs, indicated for use by women to prevent pregnancy. (See CLINICAL STUDIES (4)).

4.2 Lactation

Nursing mothers: Not recommended; can decrease milk production. (See CLINICAL STUDIES (4)).

4.3 Precautions

Co-administration with Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without asunaprevir, or paritaprevir/ritonavir/vovaltumab, with or without dasabuvir, is contraindicated. (See CLINICAL STUDIES (4)).

5.1 Headache

Intrauterine contraceptive devices (IUDs) have been demonstrated to be more effective than the COCs. (See CLINICAL STUDIES (4)).

5.2 Carbohydrate and Lipid Metabolic Effects

Norgestimate and ethinyl estradiol tablets USP should be used for the treatment of acne only if the patient desires an 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 not recommended as a form of acne treatment. (See CLINICAL STUDIES (4)).

5.3 Interference with Laboratory Tests

Norgestimate and ethinyl estradiol tablets USP should be used for the treatment of acne only if the patient desires an 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 not recommended as a form of acne treatment. (See CLINICAL STUDIES (4)).

6.1 How Supplied

Norgestimate and ethinyl estradiol tablets USP are supplied as follows: 21-day packs (42 tablets) of: 0.8 mg norgestimate and 30 mcg ethinyl estradiol. (See CLINICAL STUDIES (4)).

6.2 Postmarketing Experience

The most common adverse reactions reported during clinical trials (≥2%) were: headache, uterine bleeding, acne, dysmenorrhea, altered menses, vaginal spotting, flatulence, breast tenderness, weight increased or decreased, and respiratory infections. (See CLINICAL STUDIES (4)).

7.1 Effects of Other Drugs on Combined Oral Contraceptives

Drugs or herbal products that induce certain enzymes including CYP3A4, may decrease the effectiveness of COCs or increase the risk of breakthrough bleeding. (See CLINICAL STUDIES (4)).

7.2 Use in Specific Populations

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Norgestimate and ethinyl estradiol tablets USP should be used for the treatment of acne only if the patient desires an 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 not recommended as a form of acne treatment. (See CLINICAL STUDIES (4)).
pancreatitis when using COCs. Consider alternative contraception for women with uncontrolled dyslipidemia. A small proportion of COCs may decrease glucose tolerance. Studies suggest a small increased relative risk of developing gallbladder disease among COC users.

5.5 Gallbladder Disease

in older women with extended duration of use. The incidence of hypertension increases with increasing blood pressure rises significantly. controlled hypertension, monitor blood pressure and stop norgestimate and ethinyl estradiol tablets if

Norgestimate and ethinyl estradiol tablets are contraindicated in women with uncontrolled hypertension with vascular disease.

Studies have shown an increased risk of developing hepatocellular carcinoma in long-term (>8 years) through intra-abdominal hemorrhage.

•    Use COCs with caution in women with cardiovascular disease risk factors. This risk increases with age, particularly in women over 35 years of age who smoke. COCs have been shown to increase the risk of arterial or venous thrombotic diseases. Examples include women who are known to have a history of strokes. (Refer figure below).

•    Start norgestimate and ethinyl estradiol tablets no earlier than 4 weeks after delivery, in women who have not had a menstrual period within 2 weeks of starting therapy.

•    Pick the day label strip that starts with the first day of your period. Place this day label strip over the area that has the days of the week (starting with Sunday) pre-printed on the blister pack.

•    Start contraceptive therapy with norgestimate and ethinyl estradiol tablets USP following the cycle pack of norgestimate and ethinyl estradiol tablets USP.

•    Do not start until 4 weeks after delivery, due to the increased risk of thromboembolic disease.

8.1 Studies have shown an increased risk of developing hepatocellular carcinoma in long-term (>8 years) through intra-abdominal hemorrhage.

•    Pick the day label strip that starts with the first day of your period. Place this day label strip over the area that has the days of the week (starting with Sunday) pre-printed on the blister pack.

•    Start contraceptive therapy with norgestimate and ethinyl estradiol tablets USP following the cycle pack of norgestimate and ethinyl estradiol tablets USP.

•    Do not start until 4 weeks after delivery, due to the increased risk of thromboembolic disease.

8.1 Studies have shown an increased risk of developing hepatocellular carcinoma in long-term (>8 years) through intra-abdominal hemorrhage.
Significant changes (increase or decrease) in the plasma concentrations of estrogen and/or progestin may occur, depending on the specific drug and interaction. Monitoring the plasma concentrations of COCs may be helpful when enzyme inducers are used with COCs. The effects of enzyme inducers on plasma concentrations of COCs have been noted in some cases of co-administration with HIV protease inhibitors (decrease).

Colesevelam, a bile acid sequestrant, given together with a COC, has been shown to significantly decrease the plasma concentrations of COCs and potentially diminish the effectiveness of COCs or increase breakthrough bleeding. Some drugs or herbal products that may decrease the effectiveness of hormonal contraceptives include phenytoin, barbiturates, carbamazepine, bosentan, felbamate, and St. John’s wort. Interactions between hormonal contraceptives and other drugs may lead to breakthrough bleeding and/or contraceptive failure. Counsel women to use an alternative method of contraception or a back-up method when enzyme inducers are used with COCs, and to continue back-up contraception when reproducing patients are taking COCs containing St. John’s wort. The effects of enzyme inducers on plasma concentrations of COCs may be helpful when enzyme inducers are used with COCs. The effects of enzyme inducers on plasma concentrations of COCs have been noted in some cases of co-administration with HIV protease inhibitors (decrease).

HIV or Hepatitis C virus (HCV) protease inhibitors and non-nucleoside reverse transcriptase inhibitors (NNRTIs) may lower plasma concentrations of COCs. Women may need to be monitored for breakthrough bleeding and/or contraceptive failure if enzyme inducers are used with COCs.

The effects of enzyme inducers on plasma concentrations of COCs have been noted in some cases of co-administration with HIV protease inhibitors (decrease).

7.1 Effects of Other Drugs on Combined Oral Contraceptives

No drug-drug interaction studies were conducted with norgestimate and ethinyl estradiol tablets. However, because of the metabolic pathway through CYP3A4, it is possible that drugs that inhibit or induce this pathway may affect the plasma concentrations of norgestimate and/or ethinyl estradiol. There is substantial evidence to support the effects of drug interactions on hormone plasma concentrations. Many of the commonly used medications and herbal products may alter the plasma concentrations of COCs and subsequently affect their contraceptive effectiveness. It is important for healthcare providers to counsel women about the potential for enzyme alterations, as well as the potential for contraceptive failure when enzyme inducers are used with COCs. The effects of enzyme inducers on plasma concentrations of COCs may be helpful when enzyme inducers are used with COCs. The effects of enzyme inducers on plasma concentrations of COCs have been noted in some cases of co-administration with HIV protease inhibitors (decrease).

The following adverse reactions have been reported in patients receiving COCs: abdominoplastics (2 subjects), incontinence of urine (2 subjects), vertigo (4 subjects), chest pain (2 subjects), dyspnea (2 subjects), eczema (2 subjects), necrotic skin (2 subjects), neuropraxia (2 subjects), and pruritus (2 subjects).

The following adverse reactions have been reported from worldwide postmarketing experience: headache (3,151 subjects), vomiting (1,151 subjects), arthralgia (1,581 subjects), and abdominal pain (873 subjects). Headache occurred at a higher frequency in patients treated for a shorter duration. The incidence of headache was 2.8% in patients treated for 30 days or longer and 1.7% in patients treated for fewer than 30 days. The incidence of vomiting was 1.7% in patients treated for 30 days or longer and 1.1% in patients treated for fewer than 30 days. The incidence of arthralgia was 1.5% in patients treated for 30 days or longer and 1.3% in patients treated for fewer than 30 days. The incidence of abdominal pain was 1.2% in patients treated for 30 days or longer and 0.9% in patients treated for fewer than 30 days.

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12.2 Effects of Combined Oral Contraceptives on Other Drugs

- COCs containing EE include the synthetic 6α-estratriene compounds, such as estradiol. This study showed that Norgestimate and ethinyl estradiol tablets (NGM/EE) increased the plasma concentration of cyclosporine A.
- There were increases in plasma concentrations of cyclosporine A observed in 5 of 11 subjects treated with NGM/EE compared with placebo.
- Avoid cyclosporine A in patients treated with NGM/EE due to increased risk of systemic side effects.

12.3 Nongenotoxic Mutagenic Effects

No mutagenic effects were observed in the Ames test, mouse lymphoma assay, or the in vitro bacterial reverse mutation test (S. typhimurium TA100, TA98, TA98 with S9 metabolic activation).

13 CLINICAL PHARMACOLOGY

13.1 Precautions

- Each green placebo tablet contains only inert ingredients, as follows: FD & C Blue No. 2 aluminum lake, FD & C Blue No. 2, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone and titanium dioxide.

13.1.7 Pregnancy

COCs have been shown to decrease plasma concentrations of acetaminophen, clofibric acid, prednisolone, theophylline, tizanidine, and voriconazole) and increase their plasma concentrations. Significant decrease in plasma concentration of NGMN and NG is observed as a result of high affinity binding to SHBG, which limits its biological availability.

13.2 Breastfeeding

Advise the nursing mother to use other forms of contraception, when possible, until she has weaned her child. COCs can reduce milk production in breastfeeding mothers. This is less likely to occur once hormonal contraceptives have reached steady-state concentrations, usually within 8 to 12 weeks of COC use.

14 CLINICAL STUDIES

14.1 Contraception

NGM/EE tablets were studied for 24 cycles, providing a total of 45,244 cycles of exposure. The racial demographic composition of the study population was about 87 to 90% Caucasian, 6 to 10% African-American, with the remainder Asian (≤1%) or Other (≤1%).

14.2 Acne

100 women-years. The pregnancy rate was approximately 1 pregnancy per year. There were no exclusions on the basis of weight; the weight range for women treated was 80 to 310 lbs, with a mean weight of about 132 lbs.

14.3 Other Adverse Reactions

- Decreased blood pressure
- Increased blood pressure
- Decrease in the severity of facial acne in otherwise healthy women with this skin condition has not been observed.
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Serious blood clots are more likely to happen when you:

- smoke
- are obese
- are older than 35 years of age

Examples of serious blood clots include blood clots in the legs or eyes. Including blood clots in your lungs, heart attack, or a stroke that may lead to death. Some other data shows a statistically significant improvement in total lesions compared to those treated with placebo.

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

Read the Instructions for Use for more information about side effects.

Norgestimate and ethinyl estradiol tablets may affect the way other medicines work, and other medicines may affect the amount of norgestimate and ethinyl estradiol tablets that your body absorbs.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal products. If you think that you have been taking more medicine than you should, call your healthcare provider immediately.

Tell your healthcare provider if you:

- are breastfeeding or plan to breastfeed. Norgestimate and ethinyl estradiol tablets may decrease the amount of breast milk you make. A small amount of the hormones in norgestimate and ethinyl estradiol tablets may enter your breast milk and may affect your baby. If you are breastfeeding, your healthcare provider should discuss with you the benefits of breastfeeding and the risks of using norgestimate and ethinyl estradiol tablets.
- are pregnant or think you may be pregnant. Norgestimate and ethinyl estradiol tablets may harm your unborn baby if you take them during pregnancy.
- have certain kinds of severe migraine headaches with aura, numbness, weakness or changes in vision, or any migraine headaches if you are over 35 years of age
- have diabetes with kidney, eye, nerve, or blood vessel damage
- had a heart attack
- had a stroke
- have certain heart valve problems or irregular heart beat that increases your risk of having blood clots
- had a problem with your blood that makes it clot more than normal
- had blood clots in your arms, legs, lungs, or eyes
- smoke and are over 35 years of age

Norgestimate and ethinyl estradiol tablets may decrease the amount of breast milk you make. A small amount of the hormones in norgestimate and ethinyl estradiol tablets may enter your breast milk and may affect your baby. If you are breastfeeding, your healthcare provider should discuss with you the benefits of breastfeeding and the risks of using norgestimate and ethinyl estradiol tablets.

The amount of breast milk your baby makes depends on many factors, including the number of breast feeding your baby has each day and the amount of breast milk your baby takes at each feeding.

How should I take norgestimate and ethinyl estradiol tablets?

Read the Instructions for Use for more information about how to take your medicine.

How long should I take norgestimate and ethinyl estradiol tablets?

You should keep using this medicine as directed for at least 3 months before stopping. If you think you may become pregnant while taking this medicine, you should keep using it for at least 3 months after you stop taking it.
the first cycle that you take norgestimate and ethinyl estradiol tablets.

• Use non-hormonal back-up contraception such as condoms and spermicide for the first 7 days after implant removal or if you use the Sunday Start.

• If your period starts on a Sunday, take pill 

• Take pill 

You will use a

Sunday Start:

• Start taking norgestimate and ethinyl estradiol tablets on the day of removal of your implant or on

progestin-only method such as an implant or injection:

• If your IUD or IUS is removed on any other day, use non-hormonal back-up contraception

• If you start taking norgestimate and ethinyl estradiol tablets and you are switching from an

back-up contraception if you use the Day 1 Start.

Before the first start taking birth control pills

• Do not skip your pills, even if you do not have sex often. If you miss pills (including starting the

• Take 2 pills to make up for missed pills (see

• You may feel sick to your stomach (nauseous), especially during the first few months of taking

• If you have vomiting or diarrhea within

• Changes of color or a

bleeding or spotting may happen while you are taking norgestimate and ethinyl estradiol tablets,

• 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

• Do not use norgestimate and ethinyl estradiol tablets for a condition for which it was not prescribed. Do

• Keep norgestimate and ethinyl estradiol tablets and all medicines out of the reach of children.

• Do not use this medicine to treat any other condition unless it has been checked by your healthcare provider.

• Changes in weight

• Vaginal infections and discharge

• You should see your healthcare provider for a yearly check of your blood pressure.

• Other serious side effects include:

• trouble speaking

• chest pain

• jaundice (cholestasis), especially if you previously had cholestasis of pregnancy. Call your

• you may report side effects to the FDA at 1-800-FDA-1088 or you may also report side effects to

• You can ask your pharmacist or healthcare provider for information about norgestimate

• Do not give norgestimate and ethinyl estradiol tablets to other people, even if they have the same symptoms

• You will need to see your healthcare provider for new prescriptions for your norgestimate and ethinyl estradiol tablets. If you need a refill on prescription refills, call Lupin Pharmaceuticals, Inc. at 1-800-399-2561 or you may also report side effects to

• Inactive ingredients:

• Green pills: FD & C Blue No. 2 Aluminum Lake, croscarmellose sodium, iron oxide yellow,

• Blue pills: anhydrous lactose, FD & C Blue No. 2 Aluminum Lake, croscarmellose sodium,

• Each white, light-blue, and blue pill contains norgestimate and ethinyl estradiol. The inactive ingredients in each norgestimate and ethinyl estradiol tablet are:

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Norgestimate and ethinyl estradiol tablets come in blister packs. Read the instructions below for instructions for using your blister:

**Instructions for using your blister:**

Norgestimate and ethinyl estradiol tablets come in blister packs. Read the instructions below for instructions for using your blister:

**Day 1:**
- Remove blister from the carton.
- Take 1 tablet daily. The pill will come through a hole in the back of the blister.

**Day 2:**
- Swallow the pill. You will take 1 pill every day, at the same time each day.
- Take 1 tablet every day until you finish the pack.
- Store the blister pack in a cool dry place, out of direct sunlight.

**Day 3:**
- Take 1 tablet every day until you finish the pack.
- Take your pill at the same time each day, for 21 days, then stop for 7 days.

**Day 4:**
- Take 1 tablet every day until you finish the pack.
- If you miss a pill, take it as soon as you remember.
- If you miss 1 pill in Week 1, you do not need to use a back-up birth control method.
- If you miss a pill in any other week, use a non-hormonal birth control method (such as a condom and spermicide) as a back-up if you have sex.

**Day 5:**
- After taking the last pill on Day 28, throw out the rest of the pack and start a new pack the same day of the week, starting with Sunday.
- If your period is late, call your healthcare provider.

**Day 6:**
- Norgestimate and ethinyl estradiol tablets come in blister packs. Read the instructions below for instructions for using your blister:

**Administration:**
- This patient information and instructions for use has been approved by the U.S. Food and Drug Administration.

**Manufactured by:**
- Lupin Limited
- Pithampur (M.P.) - 454 775
- Distributed by:
- Lupin Pharmaceuticals, Inc.
- Baltimore, Maryland 21202

**Rx only**

**NDC 68180-838-71**

**Carton.**

**Blister pack containing 28 tablets packed in a pouch.**

**Pouch label**

**Image 31x113 to 161x253**

**Carton label**

**Image 31x306 to 161x361**

**Warning:**
- Keep this and all medications out of the reach of children.
- Do not use this product if you are pregnant.

**Norgestimate and ethinyl estradiol tablets USP, 0.18 mg/0.035 mg, 0.215 mg/0.035 mg and 0.25 mg/0.035 mg**

**Rx only**

**Pouch label**

**Image 31x258 to 161x301**

**Carton label**

**Image 31x306 to 161x361**

**Warning:**
- Keep this and all medications out of the reach of children.
- Do not use this product if you are pregnant.

**Norgestimate and ethinyl estradiol tablets USP, 0.18 mg/0.035 mg, 0.215 mg/0.035 mg and 0.25 mg/0.035 mg**

**Rx only**

**Pouch label**

**Image 31x258 to 161x301**

**Carton label**

**Image 31x306 to 161x361**

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**Rx only**

**Pouch label**

**Image 31x258 to 161x301**

**Carton label**

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**Rx only**

**Pouch label**

**Image 31x258 to 161x301**

**Carton label**

**Image 31x306 to 161x361**

**Warning:**
- Keep this and all medications out of the reach of children.
- Do not use this product if you are pregnant.
Norgestimate and Ethinyl Estradiol Tablets USP, 0.18 mg/0.035 mg, 0.215 mg/0.035 mg and 0.25 mg/0.035 mg

28 Tablets
Rx only

KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN. THIS PACKAGE IS NOT CHILD RESISTANT.

Pharmacist: Each unit contains information intended for the patients. This informational piece is to be provided to the patient with each prescription.

NORGESTIMATE AND ETHINYL ESTRADIOL
norgestimate and ethinyl estradiol tablet

Route of Administration
ORAL

Active Ingredient/Active Moiety
Ingredient Name Basis of Strength Strength
NORGESTIMATE (UNII: C291HFX4DY) (NORGESTIMATE - UNII:C291HFX4DY) NORGESTIMATE 0.18 mg

ETHINYL ESTRADIOL (UNII: 423D2T571U) (ETHINYL ESTRADIOL - UNII:423D2T571U) ETHINYL ESTRADIOL 0.035 mg

Inactive Ingredients
Ingredient Name Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)
HYPROMELLOSES (UNII: 3NXW29V3WO)
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)
MAGNESIUM STEARATE (UNII: 70097M6I30)
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)
POVIDONE (UNII: FZ989GH94E)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics
Color WHITE
Score no score
Shape ROUND
Size 5mm
Flavor
Imprint Code E25;LU

Marketing Information
Marketing Category ANDA
Application Number or Monograph Citation ANDA205588
Marketing Start Date 08/08/2019
Marketing End Date

Part 2 of 2
NORGESTIMATE AND ETHINYL ESTRADIOL
norgestimate and ethinyl estradiol tablet

Route of Administration
ORAL

Active Ingredient/Active Moiety
Ingredient Name Basis of Strength Strength
NORGESTIMATE (UNII: C291HFX4DY) (NORGESTIMATE - UNII:C291HFX4DY) NORGESTIMATE 0.215 mg

ETHINYL ESTRADIOL (UNII: 423D2T571U) (ETHINYL ESTRADIOL - UNII:423D2T571U) ETHINYL ESTRADIOL 0.035 mg

Inactive Ingredients
Ingredient Name Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)
HYPROMELLOSES (UNII: 3NXW29V3WO)
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)
MAGNESIUM STEARATE (UNII: 70097M6I30)
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)
POVIDONE (UNII: FZ989GH94E)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics
Color BLUE (light blue)
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Shape ROUND
Size 5mm
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<td>ETHINYL ESTRADIOL</td>
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<td>CELLULOSE, MICROCRYSTALLINE</td>
<td>(UNII: OP1R32D61U)</td>
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<tr>
<td>CROSCARMELLOSE SODIUM</td>
<td>(UNII: M28OL1HH48)</td>
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<td>FD&amp;C BLUE NO. 2</td>
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<td>HYPROMELLOSES</td>
<td>(UNII: 3NXW29V3WO)</td>
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<td>MAGNESIUM STEARATE</td>
<td>(UNII: 70097M6I30)</td>
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<td>POLYETHYLENE GLYCOL, UNSPECIFIED</td>
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Flavor: Imprint Code E27;LU

Contains Marketing Information

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Part 3 of 4

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Inert ingredients:

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Part 4 of 4

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Labeler: Lupin Pharmaceuticals, Inc. (089153071)

Registrant: Lupin Limited (675923163)