Figure A

Wallet Instructions:
Starting Levonorgestrel and Ethinyl Estradiol Tablets after Childbirth

First-trimester

2.2 How to Take Levonorgestrel and Ethinyl Estradiol Tablets

Instructions regarding missed pills, see

Levonorgestrel and ethinyl estradiol tablets are dispensed in an Extended-Cycle Wallet

Table 1 for women not currently using hormonal contraception.

Do not start until 4 weeks

starting levonorgestrel and ethinyl estradiol tablets

instructions in Table 1 for Sunday start. Use

spermicide) for the first seven days of her first

abortion or miscarriage, levonorgestrel and ethinyl estradiol tablets may

abortion or miscarriage, due to the increased

complications and potentially increase the risk

Table 1

[see Contraindications (4), Use in Specific Populations (8.4), Nursing Mothers (8.3), and FDA-Approved Patient Labeling (17)]

See Figure A.
5.6 Carbohydrate and Lipid Metabolic Effects

with a history of pregnancy-related cholestasis may be at an increased risk for COC-related cholestasis. Studies suggest a small increased relative risk of developing gallbladder disease among COC users.

An increase in blood pressure has been reported in women taking COCs, and this increase is more likely to occur with increasing concentration of progestin.

3.1.4 Impaired Liver Function

Levonorgestrel and ethinyl estradiol tablets are contraindicated in women with uncontrolled hypertension, monitor blood pressure and stop levonorgestrel and ethinyl estradiol tablets if blood pressure rises significantly.

5.4 High Blood Pressure

controlled hypertension, monitor blood pressure and stop levonorgestrel and ethinyl estradiol tablets if

Blood pressure rises significantly.

5.2.2 Risk of Liver Tumors

Liver tumors, benign or malignant, or liver disease due to COCs have been reported in women taking COCs or not taking COCs. Discontinue levonorgestrel and ethinyl estradiol tablets if liver function disturbances necessitate the discontinuation of COC use until markers of liver function return to normal and COC causation has been excluded.

5.2.3 Risk of Breast Cancer

Women who do not use COCs are at an increased risk of developing breast cancer. Women who use COCs may have a decreased risk of developing breast cancer. However, the attributable risk of breast cancer in COC users is less than one case per 10,000 woman-years. The risk of breast cancer in COC users is less than one case per 10,000 woman-years.

During clinical trials with the Hepatitis C combination drug regimen that contains dasabuvir, due to the potential for ALT elevations through intra-abdominal hemorrhage.

Do not use levonorgestrel and ethinyl estradiol tablets in women with liver disease, such as acute viral hepatitis or severe (decompensated) cirrhosis of the liver.
COCs containing EE may inhibit the metabolism of other compounds (e.g., cyclosporine, prednisolone, decrease [e.g., nevirapine] or increase [e.g., etravirine]).

Significant changes (increase or decrease) in the plasma concentrations of estrogen and/or progestin hormone concentrations.

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

Ascorbic acid and acetaminophen may increase AUC values for EE by approximately 20 to 25%. Co-administration of atorvastatin or rosuvastatin and certain COCs containing ethinyl estradiol (EE) may increase the plasma concentrations of EE.

Consult the labeling of concurrently used drugs to obtain further information about interactions with hormonal contraceptives or the potential for enzyme alterations.

Liver disease

Skin and subcutaneous tissue disorders: alopecia

Immune system disorder: hypersensitivity reactions, including itching, rash, and angioedema.

General disorders and administration site conditions: chest pain, fatigue, malaise, edema peripheral, pain

Gastrointestinal disorders: abdominal distension, vomiting

Table 3 shows the results of the clinical trial that evaluated the safety and efficacy of levonorgestrel and ethinyl estradiol tablets. Because these reactions are reported voluntarily from a population of uncertain size, they cannot be used to estimate the frequency with which the reactions occur nor can they be used to estimate the extent to which they manifest serious sequelae.

Serious Adverse Reactions:

- The following adverse reactions with the use of COCs are discussed elsewhere in the labeling:
  - Breast cancer (5.2)
  - Breast cancer may be hormonally sensitive
  - Vascular disorders: thrombosis, pulmonary embolism, pulmonary thrombosis
  - 5.1 Cancer of the Breast and Cervix
  - Both estrogen and progesterone components of COCs positively influence the incidence of cervical neoplasia.

- The use of COCs has been associated with an increase in the risk of cervical neoplasia (5.2) and cervical carcinoma (5.14).

- Women with a history of cervical dysplasia or cervical carcinoma should not use COCs.

5.14 Hereditary Angioedema

A woman who is taking COCs should have a yearly visit with her healthcare provider for a blood test to rule out or confirm the condition and to discuss options for preventing breakthrough bleeding. Some drugs or herbal products that may decrease the effectiveness of COCs or increase breakthrough bleeding and/or unscheduled bleeding and spotting include rifampicin, rifabutin, rifabutin, rufinamide, aprepitant, and products that are known to increase the metabolism of COCs (e.g., St. John's wort).

Unscheduled bleeding and unscheduled spotting decreased over successive 91-day cycles. Table 3 displays the number of days of unscheduled bleeding and spotting for each regimen.

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Days</th>
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<tr>
<td>Cycle 1 (N=385)</td>
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</tr>
<tr>
<td>Cycle 2 to 4 (N=1218)</td>
<td>10.6</td>
</tr>
<tr>
<td>Cycle 5 to 8 (N=1763)</td>
<td>8.8</td>
</tr>
</tbody>
</table>

In women with hereditary angioedema, exogenous estrogens may induce or exacerbate symptoms of angioedema. Some women with a history of angioedema may experience symptoms when taking COCs.

- The following clinical trial was conducted to evaluate the safety and efficacy of COCs in a population of African American women.

- A 12-month, randomized, multicenter, open-label study, which enrolled women aged 18 to 40, of convenience of fewer scheduled menses (4 per year instead of 13 per year) against the inconvenience of use. Women using levonorgestrel and ethinyl estradiol tablets had breast cancer because breast cancer may be hormonally sensitive. Women with a history of breast cancer were excluded from the study. More women using levonorgestrel and ethinyl estradiol tablets had breast cancer because breast cancer may be hormonally sensitive. Women with a history of breast cancer were excluded from the study. More women using levonorgestrel and ethinyl estradiol tablets had breast cancer because breast cancer may be hormonally sensitive. Women with a history of breast cancer were excluded from the study. More women using levonorgestrel and ethinyl estradiol tablets had breast cancer because breast cancer may be hormonally sensitive. Women with a history of breast cancer were excluded from the study. 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Counsel patients on the following information:

[Extracts from a medical document discussing the composition and effects of Levonorgestrel and ethinyl estradiol tablets USP, including their availability, dosage, and potential side effects.].
You may stop taking the pill whenever you wish. Consider a visit with your healthcare provider for a
What if I want to become pregnant?
However, this may be due to other reasons such as having more sexual partners.
For more information, call Lupin Pharmaceuticals, Inc. at 1-800-399-2561 or visit our website at
This Patient Information summarizes the most important information about levonorgestrel and ethinyl
symptoms that you have.
How should I store levonorgestrel and ethinyl estradiol tablets?
What are the possible serious side effects of levonorgestrel and ethinyl estradiol tablets?
Read the Instructions for Use at the end of this Patient Information.
Levonorgestrel and ethinyl estradiol tablets may affect the way other medicines work, and other
Tell your healthcare provider if you:

Levonorgestrel and ethinyl estradiol tablets are not for everyone. They are for women who:

You may report side effects to the FDA at 1-800-FDA-1088.
These are not all the possible side effects of levonorgestrel and ethinyl estradiol tablets. For more

The following chart shows the chance of getting pregnant for women who use different methods of

Your chance of getting pregnant depends on how well you follow the directions for taking your birth

What are the most common side effects of levonorgestrel and ethinyl estradiol tablets?

What should I know before using levonorgestrel and ethinyl estradiol tablets?

These are not all the possible side effects of levonorgestrel and ethinyl estradiol tablets. For more

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

If you are scheduled for any

Other serious side effects include:

Other examples of serious blood clots include

If you are pregnant or think you may

Women who start on COCs

Use a back-up or alternative

Levonorgestrel and ethinyl estradiol tablets may cause serious side

Warnings and Precautions (5.7)

If you are pregnant, breast feeding, or plan to

Women who tend to get chloasma should avoid spending a long

You may stop taking the pill whenever you wish. Consider a visit with your healthcare provider for a

What should I know before using levonorgestrel and ethinyl estradiol tablets?

How should I store levonorgestrel and ethinyl estradiol tablets?

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

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Levonorgestrel and ethinyl estradiol tablets are used by women to

What is the most important information I should know about levonorgestrel and ethinyl estradiol

Do not use levonorgestrel and ethinyl estradiol tablets if you:

How should I store levonorgestrel and ethinyl estradiol tablets?

You may report side effects to the FDA at 1-800-FDA-1088.
These are not all the possible side effects of levonorgestrel and ethinyl estradiol tablets. For more

What should I know before using levonorgestrel and ethinyl estradiol tablets?

Other serious side effects include:

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Your chance of getting pregnant depends on how well you follow the directions for taking your birth

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Other serious side effects include:

Other serious side effects include:

What should I know before using levonorgestrel and ethinyl estradiol tablets?
If you miss two pink pills in a row, follow these steps:

What should I do if I miss any levonorgestrel and ethinyl estradiol pills?

Sunday Start:

Instructions for using your levonorgestrel and ethinyl estradiol tablets Extended-Cycle Wallet:

When should I start taking levonorgestrel and ethinyl estradiol tablets?

Before you start taking levonorgestrel and ethinyl estradiol tablets:

What should I know about my period when taking levonorgestrel and ethinyl estradiol tablets?
You could become pregnant if you have sex in the 7 days after you miss two pills. You must use a non-hormonal birth control method (such as a condom or spermicide) as a back-up if you have sex during the first 7 days after you restart your pills.

If you miss 3 or more pink pills in a row, follow these steps:
Do not take the missed pills. Keep taking 1 pill every day until you have completed all of the remaining pills in the pack. For example, if you start taking the pill on Thursday, take the pill under "Thursday" and do not take the missed pills. You may have bleeding during the week following the missed pills.

You could become pregnant if you have sex during the days of missed pills or during the first 7 days after restarting your pills. You must use a non-hormonal birth control method (such as a condom or spermicide) as a back-up when you miss pills and for the first 7 days after you restart your pills. If you do not have your period when you are taking the white pills, call your healthcare provider.

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

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

Distributed by: Lupin Pharmaceuticals, Inc.
Baltimore, Maryland 21202 United States
Manufactured by: Lupin Limited
Pithampur (M.P.) - 454 775 INDIA
Revised: January 2018 ID#: 253448

LEVONORGESTREL AND ETHINYL ESTRADIOL
levonorgestrel and ethinyl estradiol

carton label

levonorgestrel and ethinyl estradiol tablets USP, 0.15 mg/0.03 mg
Rx only
wallet label - extended-cycle wallet of 91 tablets
NDC 68180-843-11

levonorgestrel and ethinyl estradiol tablets USP, 0.15 mg/0.03 mg
Rx only
Pouch label - contains extended-cycle wallet of 91 tablets
NDC 68180-843-11

levonorgestrel and ethinyl estradiol tablets USP, 0.15 mg/0.03 mg
Rx only
Carton label - contains 3 pouches each containing one extended-cycle wallet of 91 tablets
NDC 68180-843-13
### Inactive Ingredients

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<td>CELLULOSE, MICROCRYSTALLINE</td>
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<tr>
<td>CROSCARMELLOSE SODIUM</td>
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<tr>
<td>FD&amp;C RED NO. 40</td>
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<td>HYPROMELLOSE 2910 (6 MPA.S)</td>
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<tr>
<td>MAGNESIUM STEARATE</td>
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### Product Characteristics

- **Color**: Pink (Pink)
- **Score**: no score
- **Shape**: Round (Round)
- **Size**: 6mm
- **Flavor**: Imprint Code: LU;U21

### Marketing Information

**Marketing Category**: ANDA

**Application Number or Monograph Citation**: ANDA091440

**Marketing Start Date**: 10/24/2012

**Marketing End Date**: 

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**Product Information**

**Route of Administration**: ORAL

**Inactive Ingredients**

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<th>Ingredient Name</th>
<th>Strength</th>
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<td>MAGNESIUM STEARATE</td>
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### Product Characteristics

- **Color**: White (White to Off White)
- **Score**: no score
- **Shape**: Round (Round)
- **Size**: 6mm

### Marketing Information

**Marketing Category**: ANDA

**Application Number or Monograph Citation**: ANDA091440

**Marketing Start Date**: 10/24/2012

**Marketing End Date**: 

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**Labeler**

- **Registrant**: Lupin Pharmaceuticals, Inc. (089153071)

**Establishment**

- **Name**: LUPIN LIMITED
- **Address**: 650582310
- **ID/FEI**: MANUFACTURE(68180-843)

**Revised**: 2/2019