NORGESTIMATE AND ETHINYL ESTRADIOL tablets USP.

Contraception

- Norgestimate and ethinyl estradiol tablets USP are indicated for use by females of reproductive age to suppress ovulation.
- Norgestimate and ethinyl estradiol tablets USP should be used for the treatment of acne only if the patient desires an oral contraceptive method.
- Norgestimate and ethinyl estradiol tablets USP are also indicated for the treatment of moderate acne vulgaris in females at least 15 years of age, who have no known contraindications to oral contraceptive therapy and have achieved menarche.

Warnings and Precautions

- Evaluate significant change in headaches and discontinue norgestimate and ethinyl estradiol tablets if blood pressure rises significantly.
- Discontinue norgestimate and ethinyl estradiol tablets if jaundice occurs.
- Evaluate irregular bleeding or amenorrhea.
- Monitor prediabetic and diabetic women taking norgestimate and ethinyl estradiol tablets.
- Evaluate significant change in weight (including weight increased or decreased).
- Evaluate genital discharge, changes in weight (including weight increased or decreased), vaginal infection, abdominal/gastrointestinal pain, mood disorders (including mood alteration and depression), breast complaints (including mastodynia), and other complaints (including thrombotic event).

HOW SUPPLIED/STORAGE AND HANDLING

- Norgestimate and ethinyl estradiol tablets USP active tablets are 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 stored at controlled room temperature.

Injection

- Norgestimate and ethinyl estradiol tablets USP are indicated for use by females of reproductive age to suppress ovulation.
- Norgestimate and ethinyl estradiol tablets USP should be used for the treatment of acne only if the patient desires an oral contraceptive method.
- Norgestimate and ethinyl estradiol tablets USP are also indicated for the treatment of moderate acne vulgaris in females at least 15 years of age, who have no known contraindications to oral contraceptive therapy and have achieved menarche.
or severity of migraine during COC use (which may be prodromal of a cerebrovascular event).

If a woman taking norgestimate and ethinyl estradiol tablets develops new headaches that are recurrent, women with hypertriglyceridemia, or a family history thereof, may be at an increased risk of Women will have adverse lipid changes while on COCs.

Consider alternative contraception for women with uncontrolled dyslipidemia. A small proportion of COCs may decrease glucose tolerance.

5.6 Carbohydrate and Lipid Metabolic Effects

Use of COCs may worsen existing gallbladder disease. A past history of COC-related cholestasis is more frequent in women using ethinyl estradiol-containing medications, such as COCs. Discontinue o   Have headaches with focal neurological symptoms or migraine headaches with aura o   Have cerebrovascular disease o   Have inherited or acquired hypercoagulopathies

Table 2: Instructions for Missed Norgestimate and Ethinyl Estradiol Tablets USP

Table 8.1

<table>
<thead>
<tr>
<th>Tablet</th>
<th>Week</th>
<th>Days</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>7</td>
<td>Take pill 2</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>7</td>
<td>Take pill 3</td>
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<td>Take pill 6</td>
</tr>
<tr>
<td>6</td>
<td>1</td>
<td>7</td>
<td>Take pill 7</td>
</tr>
</tbody>
</table>

WARNINGS AND PRECAUTIONS

5.1 Contraindications and Other Vacuum Problems

• Pregnancy, because there is no reason to use COCs during pregnancy
• Undiagnosed abnormal uterine bleeding
• Serious cardiac, hepatic, renal, or hematologic disease
• Known or suspected carcinoma
• Impaired liver function
• Known or suspected estrogen-dependent neoplasia
• Hypertriglyceridemia

5.2 Cerebrovascular Disease

The risk of cerebrovascular disease increases with age, particularly in women over 35 years of age who smoke.

5.3 Risk of Liver Enzyme Elevations with Concomitant Hepatitis C Treatment

Studies have shown an increased risk of developing hepatocellular carcinoma in long-term (>8 years) users of COCs. Hepatitis C may be exacerbated by COC therapy.

5.4 Hepatic Tumors

Norgestimate and ethinyl estradiol tablets are contraindicated in women with benign and malignant liver tumors.

5.5 Gallbladder Disease

An increase in blood pressure has been reported in women taking COCs, and this increase is more likely to occur in women using ethinyl estradiol-containing medications, such as COCs.

5.7 Pregnancy

Use of COCs may worsen existing gallbladder disease. A past history of COC-related cholestasis is more frequent in women using ethinyl estradiol-containing medications, such as COCs. Discontinue

5.8 Breast Cancer

Breast cancer is a rare event with use of nonhormonal contraceptives. Breast cancer is a rare event with use of nonhormonal contraceptives.

5.9 Thromboembolic Disease

The risk of thromboembolic disease increases with age, particularly in women over 35 years of age who smoke.

5.11 Use in Women with a History of VTE

Use of COCs may increase the risk of VTE. The risk of VTE is highest during the first year of use of COCs and when restarting COCs gradually disappears after use is discontinued.

5.15 Pregnancy

Use of COCs may increase the risk of VTE. The risk of VTE is highest during the first year of use of COCs and when restarting

8.1 Norgestimate and Ethinyl Estradiol Tablets USP

Table 8.1

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11.2 Contraindications

• Pregnancy
• Undiagnosed abnormal uterine bleeding

11.3 Cerebrovascular Disease

The risk of cerebrovascular disease increases with age, particularly in women over 35 years of age who smoke.

11.4 Hepatic Tumors

Norgestimate and ethinyl estradiol tablets are contraindicated in women with benign and malignant liver tumors.

11.5 Gallbladder Disease

An increase in blood pressure has been reported in women taking COCs, and this increase is more likely to occur in women using ethinyl estradiol-containing medications, such as COCs.

11.7 Pregnancy

Use of COCs may increase the risk of VTE. The risk of VTE is highest during the first year of use of COCs and when restarting

11.11 Use in Women with a History of VTE

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11.2 Contraindications

• Pregnancy
• Undiagnosed abnormal uterine bleeding

11.3 Cerebrovascular Disease

The risk of cerebrovascular disease increases with age, particularly in women over 35 years of age who smoke.

11.4 Hepatic Tumors

Norgestimate and ethinyl estradiol tablets are contraindicated in women with benign and malignant liver tumors.
5.2 Effects of Combined Oral Contraceptives on Other Drugs

Substances increasing the plasma concentrations of COCs include phenytoin, barbiturates, carbamazepine, bosentan, felbamate, and ethanol. The effect of norgestimate and ethinyl estradiol tablets is additive with the effect of any of these substances. The risk of adverse events increases if these drugs are used concomitantly.

5.3 Contraindications

The estrogen component of COCs may raise the serum concentrations of thyroxine-binding globulin, which may result in decreased serum free thyroxine concentrations. Such findings may be due to differences in sexual behavior and other factors.

5.11 Carcinoma of Breast and Cervix

Carefully observe women with a history of breast cancer and discontinue norgestimate and ethinyl estradiol tablets if depression recurs to a serious degree. Carefully observe women with a history of depression and discontinue norgestimate and ethinyl estradiol tablets if depression recurs to a serious degree. Carefully observe women with a history of depression and discontinue norgestimate and ethinyl estradiol tablets if depression recurs to a serious degree. Carefully observe women with a history of depression and discontinue norgestimate and ethinyl estradiol tablets if depression recurs to a serious degree.

6 ADVERSE REACTIONS

6.1 Clinical Trial Experience

In clinical trials of norgestimate and ethinyl estradiol tablets, the frequency and duration of breakthrough bleeding and/or spotting were similar to those with other COCs. However, there was a tendency for breakthrough bleeding and/or spotting to occur more frequently in the first year of use compared to subsequent years of use. In a 1-year study of 2,364 women using norgestimate and ethinyl estradiol tablets, the incidence of breakthrough bleeding and/or spotting was 13.5% in the first year of use and 9.7% in subsequent years of use.

6.2 Postmarketing Experience

Serious adverse reactions include, but are not limited to, the following:

- Breast cancer (1 subject)
- Carcinoma of the cervix in situ (1 subject)
- Hypertension (1 subject)
- Mortality (1 subject)

The following additional adverse reactions have been reported from worldwide postmarketing experience with norgestimate and ethinyl estradiol tablets:

- Chest pain
- Angina
- Myocardial infarction
- Pulmonary embolism
- Deep vein thrombosis
- Stroke
- Other cardiovascular events

6.3 Laboratory Abnormalities

In clinical trials of norgestimate and ethinyl estradiol tablets, laboratory abnormalities were comparable to those observed in control groups and did not lead to drug discontinuation.

6.4 Special Populations

Adverse reactions commonly reported by COC users are:

- Liver disease
- Adverse reactions commonly reported by COC users are:

5.15 Chloasma

Women who use norgestimate and ethinyl estradiol tablets may experience amenorrhea. Some women may experience amenorrhea after discontinuation of COCs, especially when such a regimen and misses two consecutive periods, rule out pregnancy.

5.8 Bleeding Irregularities and Amenorrhea

In clinical trials of norgestimate and ethinyl estradiol tablets, the frequency and duration of breakthrough bleeding and/or spotting were similar to those with other COCs. However, there was a tendency for breakthrough bleeding and/or spotting to occur more frequently in the first year of use compared to subsequent years of use. In a 1-year study of 2,364 women using norgestimate and ethinyl estradiol tablets, the incidence of breakthrough bleeding and/or spotting was 13.5% in the first year of use and 9.7% in subsequent years of use.

5.9 Effects of Combined Oral Contraceptives on Other Oral Contraceptives

Co-administration of norgestimate and ethinyl estradiol tablets with hormonal contraceptives may result in increased serum concentrations of the estrogen component and decreased serum concentrations of the progestin component. The effect of norgestimate and ethinyl estradiol tablets is additive with the effect of any of these substances. The risk of adverse events increases if these drugs are used concomitantly.

5.12 Other Drugs and Contraceptive Use

Norgestimate and ethinyl estradiol tablets are contraindicated for use during the postpartum period because of the increased risk of thrombotic and thromboembolic events in this population.

5.13 Monitoring

The following adverse reactions have been reported from worldwide postmarketing experience with norgestimate and ethinyl estradiol tablets:

- Chest pain
- Angina
- Myocardial infarction
- Pulmonary embolism
- Deep vein thrombosis
- Stroke
- Other cardiovascular events

5.14 Breastfeeding

In clinical trials of norgestimate and ethinyl estradiol tablets, breast feeding was discontinued in 2.7% of women due to adverse reactions, including breast engorgement, breast tenderness, and breast pain. Breastfeeding may decrease the risk of breast cancer in women who take COCs and should be encouraged.

6.1 Clinical Trial Experience

In clinical trials of norgestimate and ethinyl estradiol tablets, the frequency and duration of breakthrough bleeding and/or spotting were similar to those with other COCs. However, there was a tendency for breakthrough bleeding and/or spotting to occur more frequently in the first year of use compared to subsequent years of use. In a 1-year study of 2,364 women using norgestimate and ethinyl estradiol tablets, the incidence of breakthrough bleeding and/or spotting was 13.5% in the first year of use and 9.7% in subsequent years of use.

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The following additional adverse reactions have been reported from worldwide postmarketing experience with norgestimate and ethinyl estradiol tablets:

- Chest pain
- Angina
- Myocardial infarction
- Pulmonary embolism
- Deep vein thrombosis
- Stroke
- Other cardiovascular events
Acne vulgaris is a disorder of the pilosebaceous unit characterized by the formation of comedones, inflammatory lesions, and non-inflammatory lesions.

Norgestimate and ethinyl estradiol tablets were evaluated for the treatment of acne vulgaris in two randomized, double-blind, placebo-controlled, multicenter, six- (28 day) cycle studies. Two hundred women-years.

The racial demographic was about 87 to 90% Caucasian, 6 to 10% African-American, with the remainder Asian (≤1%) or Other.

In four clinical trials with norgestimate and ethinyl estradiol tablets, 4,756 women aged 15 to 41 years were studied for 24 cycles, providing a total of 45,244 cycles of exposure. The racial demographic was about 87 to 90% Caucasian, 6 to 10% African-American, with the remainder Asian (≤1%) or Other.

The pharmacodynamics of the combination of norgestimate and ethinyl estradiol have been documented in women with clear evidence of a variety of factors, including age, race, and ethnicity. The pharmacodynamics of norgestimate and ethinyl estradiol tablets have been established in women of reproductive age.

There was no significant difference between norgestimate and ethinyl estradiol tablets and placebo in terms of the incidence of acne.

The pharmacodynamics of norgestimate and ethinyl estradiol tablets have been established in women of reproductive age.

The pharmacodynamics of norgestimate and ethinyl estradiol tablets have been established in women of reproductive age.

Table 1: Summary of Pharmacokinetic Parameters of Norgestimate (NG) and Ethinyl Estradiol (EE) Tablets During a Three-Month Treatment Cycle

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<th>Analyte</th>
<th>Tmax (h)</th>
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<td>Ethinyl estradiol</td>
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The pharmacokinetics of norgestimate and ethinyl estradiol tablets have been established in women of reproductive age.

The use of contraceptive steroids may influence the results of certain laboratory tests, such as the serum concentration of thyroid-binding globulin.

Table 2: Summary of Pharmacokinetic Parameters of Norgestimate (NG) and Ethinyl Estradiol (EE) Tablets During a Three-Month Treatment Cycle

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Table 3: Summary of Pharmacokinetic Parameters of Norgestimate (NG) and Ethinyl Estradiol (EE) Tablets During a Three-Month Treatment Cycle

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The use of contraceptive steroids may influence the results of certain laboratory tests, such as the serum concentration of thyroid-binding globulin.
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.
- blood clots in your lungs, heart attack, or a stroke that may lead to death.

Some other serious side effects that may lead to death, including serious cardiovascular side effects, include:

- vision loss
- headache
- cancer

Serious blood clots can happen especially if you smoke, are obese, or are older than 35 years of age.

Read the Instructions for Use

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.

Tell your healthcare provider about all the medicines you take,

Progestin-only (ministered as a ring)

Don't smoke.

Some possible serious side effects of norgestimate and ethinyl estradiol tablets include:

- blood clots in your lungs, heart attack, or a stroke
- blood clots in your brain
- blood clots in your legs or eyes
- vision loss
- eye problems
- headache
- vision changes
- cancer
- breast cancer
- blood cancer
- change in blood clots
- risk of stroke
- risk of having blood clots
- blood clotting problems

Who should not take norgestimate and ethinyl estradiol tablets?

Do not take norgestimate and ethinyl estradiol tablets if you:

- are allergic to norgestimate or ethinyl estradiol
- have had a blood clot in your lungs or blood clots in your other organs
- have had cancer of the breast or any other cancer that is sensitive to female hormones
- are pregnant
- smoke and are over 35 years of age
- have diabetes with kidney, eye, nerve, or blood vessel damage
- have high blood pressure that cannot be controlled by medicine
- had a heart attack
- have had a problem with your blood that makes it clot more than normal
- had breast cancer or any cancer that is sensitive to female hormones
- are over 35 years of age
- are pregnant or think you may be pregnant
- are breastfeeding

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

READ this Patient Information and Instructions for Use at the end of this Patient Information.

BOXED WARNING

Norgestimate and ethinyl estradiol tablets may cause serious side effects, including:

- blood clots in your lungs or blood clots in your other organs
- vision loss
- eye problems
- headache
- vision changes
- cancer
- breast cancer
- blood cancer
- change in blood clots
- risk of stroke
- risk of having blood clots
- blood clotting problems

Progestin-only (ministered as a ring)

Don't smoke.
the same day of the week as the first pack. Take the first pill in the new pack whether or not you are having your period.

•    After taking the last pill on the day when you would have had your next injection.
•    Start taking norgestimate and ethinyl estradiol tablets on the day of removal of your implant or on the day you would have reapplied the next pack of your previous birth control method.
•    Start your new norgestimate and ethinyl estradiol tablets pack on the same day that you would start your next pack of your previous birth control method before:
  •    If you use the Sunday Start, use non-hormonal back-up contraception such as condoms and spermicide during the first 7 days of using norgestimate and ethinyl estradiol tablets.
  •    If you use the Day 1 Start, use non-hormonal back-up contraception such as condoms and spermicide during the first 7 days of using norgestimate and ethinyl estradiol tablets.
  •    If you start taking norgestimate and ethinyl estradiol tablets and you are switching from another form of contraception (like condoms and spermicide) during this time period.

When should I start taking norgestimate and ethinyl estradiol tablets?

•    There are 2 ways to start taking your birth control pills. You can either start on a Sunday (Sunday Start) or start your birth control pills on any other day of the week. The more common side effects of norgestimate and ethinyl estradiol tablets:
  •    nausea in the morning
  •    heartburn or indigestion
  •    breast tenderness or swelling
  •    milk flow from breasts
  •    water retention
  •    weight gain
  •    depression
  •    acne
  •    changes in menses

•    The problem will usually go away. If your nausea does not go away, call your healthcare provider.

•    Call your healthcare provider if you have a swollen face, lips, mouth tongue or throat, which may lead to trouble breathing or choking, or you have difficulty swallowing or speaking. This could be a sign of a rare but serious condition called angioedema. Call your healthcare provider if you have yellowing of your skin or eyes.

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

•    Before you start using norgestimate and ethinyl estradiol tablets, tell your healthcare provider about all the medicines you take or plan to take, including prescription and nonprescription medicines, vitamins, and herbal supplements. You should not use birth control pills if you are pregnant or if you have had certain medical conditions, including certain forms of cancer.

•    Do not give norgestimate and ethinyl estradiol tablets to other people, even if they have the same symptoms. It is especially important not to give norgestimate and ethinyl estradiol tablets to other women.

•    Store norgestimate and ethinyl estradiol tablets at room temperature between 68°F to 77°F (20°C to 25°C).

How should I store norgestimate and ethinyl estradiol tablets?

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

•    White pills: anhydrous lactose, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone and titanium dioxide.

•    Each brown, green, blue-white, and blue tablet contains norgestimate and ethinyl estradiol and ethinyl estradiol. The inactive ingredients in norgestimate and ethinyl estradiol tablets are:

•    White pills: anhydrous lactose, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone and titanium dioxide.

•    Orange tablets: lactose monohydrate, hypromellose, microcrystalline cellulose, povidone, magnesium stearate, iron oxide yellow, titanium dioxide.

•    Blue tablets: lactose monohydrate, hypromellose, microcrystalline cellulose, povidone and magnesium stearate.

•    Brown tablets: lactose monohydrate, hypromellose, microcrystalline cellulose, povidone and magnesium stearate.

•    Black tablets: lactose monohydrate, microcrystalline cellulose, povidone and magnesium stearate.

•    Each blue and white pill contains norgestimate and ethinyl estradiol. Each blue and yellow tablet contains norgestimate and ethinyl estradiol. The inactive ingredients in norgestimate and ethinyl estradiol tablets are:

•    White pills: anhydrous lactose, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone and titanium dioxide.

•    Blue and white tablets: lactose monohydrate, microcrystalline cellulose, povidone, hypromellose, croscarmellose sodium, and titanium dioxide.

•    Blue tablets: lactose monohydrate, microcrystalline cellulose, povidone and magnesium stearate.

•    Each tablet contains norgestimate and ethinyl estradiol. The inactive ingredients in norgestimate and ethinyl estradiol tablets are:

•    White tablets: anhydrous lactose, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone and magnesium stearate.

•    Each brown tablet contains norgestimate and ethinyl estradiol. The inactive ingredients in norgestimate and ethinyl estradiol tablets are:

•    White tablets: anhydrous lactose, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone and magnesium stearate.

•    Each blue tablet contains norgestimate and ethinyl estradiol. The inactive ingredients in norgestimate and ethinyl estradiol tablets are:

•    White tablets: anhydrous lactose, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone and magnesium stearate.

•    Each brown tablet contains norgestimate and ethinyl estradiol. The inactive ingredients in norgestimate and ethinyl estradiol tablets are:

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•    Each blue tablet contains norgestimate and ethinyl estradiol. The inactive ingredients in norgestimate and ethinyl estradiol tablets are:

•    White tablets: anhydrous lactose, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone and magnesium stearate.
WHAT TO DO IF YOU MISS A PILL

If you miss a pill:

• If you miss 1 pill in Weeks 1, 2, or 3, follow these steps:
  - Take 1 pill immediately, at any time. Take your next pill at your regular time.
• If you miss 2 pills in Week 1 or Week 2 of your pack, follow these steps:
  - Stop taking your pills, but do not throw out the rest of the pack. Throw out the rest of the pack and start a new pack that same day.
• 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, follow these steps:
  - Stop taking your pills, but do not throw out the rest of the pack. Throw out the rest of the pack and start a new pack that same day.

If you miss 3 or more pills:

• You must use a non-hormonal birth control method (such as a condom and spermicide) as a back-up 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.

• You may not have your period this month but this is expected. However, if you miss your period 2 months in a row, call your healthcare provider because you might be pregnant.

• You should use a non-hormonal method of birth control (such as a condom and spermicide) as a back-up if you have sex during the first 7 days after you restart your pills.

• Throw out the rest of the pill pack and start a new pack that same day.
Lupin Pharmaceuticals, Inc.

LACTOSE MONOHYDRATE
(UNII: EWQ57Q8I5X)
MAGNESIUM STEARATE
(UNII: 70097M6I30)
POLYETHYLENE GLYCOLS
(UNII: 3WJQ0SDW1A)
POVIDONE
(UNII: FZ989GH94E)
TITANIUM DIOXIDE
(UNII: 15FIX9V2JP)

Product Characteristics

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

Contains

Marketing Information

Marketing Category | Application Number or Monograph Citation | ANDA
Marketing Start Date | 07/18/2016
Marketing End Date

ANDA

ANDA205588

Part 4 of 4

INERT
inert
tablet

Product Information

Route of Administration | ORAL

Inactive Ingredients

Ingredient Name | Strength
CELLULOSE, MICROCRYSTALLINE
CROSCARMELLOSE SODIUM
FD&C BLUE NO. 2
FERRIC OXIDE YELLOW
HYPROMELLOSES
LACTOSE MONOHYDRATE
MAGNESIUM STEARATE
POLYETHYLENE GLYCOLS
TITANIUM DIOXIDE