JAIMIESS- levonorgestrel / ethinyl estradiol and ethinyl estradiol
Bryant Ranch Prepack

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use Jaimiess safely and effectively. See full prescribing information for Jaimiess.

Jaimiess®
Levonorgestrel and Ethinyl Estradiol Tablets, USP and Ethinyl Estradiol Tablets, USP
0.15 mg/0.03 mg and 0.01 mg

for oral use
Initial U.S. Approval: 1982

WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS

See full prescribing information for complete boxed warning.

- **Women over 35 years old who smoke should not use norethindrone acetate and ethinyl estradiol tablets and ferrous fumarate tablets (4)**
- **Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptive (COC) use (4)**

RECENT MAJOR CHANGES

Warnings and Precautions, Malignant Neoplasms (5.2) 04/2022

INDICATIONS AND USAGE

Jaimiess is an estrogen/progestin COC indicated for use by women to prevent pregnancy.(1)

DOSAGE AND ADMINISTRATION

Take one tablet daily by mouth at the same time every day for 91 days. (2)

DOSAGE FORMS AND STRENGTHS

Jaimiess consists of 84 peach tablets containing 0.15 mg levonorgestrel and 0.03 mg ethinyl estradiol, and 7 yellow tablets containing 0.01 mg ethinyl estradiol. (3)

CONTRAINDICATIONS

- A high risk of arterial or venous thrombotic diseases (4)
- Undiagnosed abnormal genital bleeding (4)
- Breast cancer or other estrogen- or progestin-sensitive cancer (4)
- Liver tumors or liver disease (4)
- Pregnancy (4)
- Co-administration with hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir (4)

WARNINGS AND PRECAUTIONS

- ***Vascular risks***: Stop Jaimiess if a thrombotic event occurs. Stop Jaimiess atleast 4 weeks before and through 2 weeks after major surgery. Start Jaimiess no earlier than 4 weeks after delivery, in women who are not breastfeeding. (5.1)
- ***Liver disease:*** Discontinue Jaimiess if jaundice occurs. (5.3)
- |***High blood pressure:*** Do not prescribe Jaimiess for women with uncontrolled hypertension or hypertension with vascular disease. (5.5)
- |***Carbohydrate and lipid metabolic effects:*** Monitor prediabetic and diabetic women taking Jaimiess. Consider an alternate contraceptive method for women with uncontrolled dyslipidemias. (5.7)
- |***Headache:*** Evaluate significant change in headaches and discontinue Jaimiess if indicated. (5.8)
- |***Uterine bleeding***: Evaluate irregular bleeding or amenorrhea. (5.9)

ADVERSE REACTIONS

The most common adverse reactions (≥5%) in clinical trials for Jaimiess are irregular and/or heavy uterine bleeding, weight gain, and acne. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Xiromed, LLC at 1-844-XIROMED (1-844-947-6633) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

Drugs or herbal products that induce certain enzymes, including CYP3A4, may decrease the effectiveness of COCs or increase breakthrough bleeding. Counsel patients to use a back-up method or alternative method of contraception when enzyme inducers are used with COCs. (7.1)

USE IN SPECIFIC POPULATIONS

•Nursing Mothers: Not recommended for nursing mothers; can decrease milk production. (8.3)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 1/2024

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS

Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptives (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 should not be used by women who are over 35 years of age and smoke. [See CONTRAINDICATIONS (4).]

1 INDICATIONS AND USAGE

Jaimiess® is indicated for use by women to prevent pregnancy.

2 DOSAGE AND ADMINISTRATION

Take one tablet by mouth at the same time every day. The dosage of Jaimiess is one peach tablet containing levonorgestrel and ethinyl estradiol daily for 84 consecutive days, followed by one yellow ethinyl estradiol tablet for 7 days. To achieve maximum contraceptive effectiveness, Jaimiess must be taken exactly as directed and at intervals not exceeding 24 hours.

Instruct the patient to begin taking Jaimiess on the first Sunday after the onset of menstruation. If menstruation begins on a Sunday, the first peach tablet is taken that day. One peach tablet should be taken daily for 84 consecutive days, followed by one yellow tablet for 7 consecutive days. A non-hormonal back-up method of contraception (such as condoms or spermicide) should be used until a peach tablet has been taken daily for 7 consecutive days. A scheduled period should occur during the 7 days that the yellow tablets are taken.

Begin the next and all subsequent 91-day cycles without interruption on the same day of the week (Sunday) on which the patient began her first dose of Jaimiess following the

same schedule: 84 days taking a peach tablet followed by 7 days taking a yellow tablet. If the patient does not immediately start her next pill pack, she should protect herself from pregnancy by using a non-hormonal back-up method of contraception until she has taken a peach tablet daily for 7 consecutive days.

If unscheduled spotting or bleeding occurs, instruct the patient to continue on the same regimen.

If the bleeding is persistent or prolonged, advise the patient to consult her healthcare provider.

For patient instructions regarding missed pills, see *FDA-Approved Patient Labeling*.

For postpartum women who are not breastfeeding, start Jaimiess no earlier than four to six weeks postpartum due to increased risk of thromboembolism. If the patient starts on Jaimiess postpartum and has not yet had a period, evaluate for possible pregnancy, and instruct her to use an additional method of contraception until she has taken a peach tablet for 7 consecutive days.

3 DOSAGE FORMS AND STRENGTHS

Jaimiess tablets (levonorgestrel/ethinyl estradiol tablets, USP and ethinyl estradiol tablets, USP) are available in Extended-Cycle Tablet Dispensers, each containing a 13-week supply of tablets: 84 peach tablets, each containing 0.15 mg of levonorgestrel and 0.03 mg ethinyl estradiol, and 7 yellow tablets each containing 0.01 mg of ethinyl estradiol. The peach tablets are round, film-coated, debossed with **SZ** on one side and **J4** on the other side. The yellow tablets are round, film-coated, debossed with **SZ** on one side and **L1** on the other side.

4 CONTRAINDICATIONS

Jaimiess is contraindicated in females who are known to have or develop the following conditions:

A high risk of arterial or venous thrombotic diseases. Examples include women who are known to:

- Smoke, if over age 35 [see **BOXED WARNING and WARNINGS AND PRECAUTIONS (5.1)**].
- Have deep vein thrombosis or pulmonary embolism, now or in the past [see **WARNINGS AND PRECAUTIONS (5.1)**].
- Have cerebrovascular disease [see **WARNINGS AND PRECAUTIONS (5.1)].**
- Have coronary artery disease [see **WARNINGS AND PRECAUTIONS (5.1)].**
- Have thrombogenic valvular or thrombogenic rhythm diseases of the heart (for example, subacute bacterial endocarditis

  with valvular disease, or atrial fibrillation) [see **WARNINGS AND PRECAUTIONS (5.1)**]
- Have inherited or acquired hypercoagulopathies [see **WARNINGS AND PRECAUTIONS (5.1)].**

◦ Have uncontrolled hypertension [see **WARNINGS AND PRECAUTIONS (5.5)].**

◦ Have diabetes with vascular disease [see **WARNINGS AND PRECAUTIONS (5.7)].**

◦ Have headaches with focal neurological symptoms or have migraine headaches with or without aura if over age 35

[see **WARNINGS AND PRECAUTIONS (5.8)]**.

- Undiagnosed abnormal genital bleeding [see **WARNINGS AND PRECAUTIONS (5.9)**].
- Current diagnosis of, or history of, breast cancer, which may be hormone-sensitive. [see **WARNINGS AND PRECAUTIONS (5.2)**].
- Liver tumors, benign or malignant, or liver disease [see **WARNINGS AND PRECAUTIONS (5.3) AND USE IN SPECIFIC POPULATIONS (8.6)].**
- Pregnancy, because there is no reason to use COCs during pregnancy [see **WARNINGS AND PRECAUTIONS (5.10) AND USE IN SPECIFIC POPULATIONS (8.1)].**
- Use of Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, due to the potential for ALT elevations [see **WARNINGS AND PRECAUTIONS (5.4)].**

5 WARNINGS AND PRECAUTIONS

5.1 Thrombotic and Other Vascular Events

Stop Jaimiess if an arterial or deep venous thrombotic event occurs. Although the use of COCs increases the risk of venous thromboembolism, pregnancy increases the risk of venous thromboembolism as much or more than the use of COCs. The risk of venous thromboembolism in women using COCs is 3 to 9 per 10,000 woman-years. The excess risk is highest during the first year of use of a COC. Use of COCs also increases the risk of arterial thromboses such as strokes and myocardial infarctions, especially in women with other risk factors for these events. The risk of thromboembolic disease due to COCs gradually disappears after COC use is discontinued.

Use of Jaimiess provides women with more hormonal exposure on a yearly basis than conventional monthly oral contraceptives containing the same strength synthetic estrogens and progestins (an additional 9 and 13 weeks of exposure to progestin and estrogen, respectively, per year).

If feasible, stop Jaimiess at least 4 weeks before and through 2 weeks after major surgery or other surgeries known to have an elevated risk of thromboembolism.

Start Jaimiess no earlier than 4 to 6 weeks after delivery, in women who are not breastfeeding. The risk of postpartum thromboembolism decreases after the third postpartum week, whereas the risk of ovulation increases after the third postpartum week.

COCs have been shown to increase both the relative and attributable risks of cerebrovascular events (thrombotic and hemorrhagic strokes), although, in general, the risk is greatest among older (>35 years of age), and hypertensive women who also smoke. COCs also increase the risk for stroke in women with other underlying risk

factors.

Oral contraceptives must be used with caution in women with cardiovascular disease risk factors.

Stop Jaimiess if there is unexplained loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions. Evaluate for retinal vein thrombosis immediately.

5.2 Malignant Neoplasms

Breast Cancer

Jaimiess is contraindicated in females who currently have or have had breast cancer because breast cancer may be hormonally sensitive *[see Contraindications (4)].*

Epidemiology studies have not found a consistent association between use of combined oral contraceptives (COCs) and breast cancer risk. Studies do not show an association between ever (current or past) use of COCs and risk of breast cancer. However, some studies report a small increase in the risk of breast cancer among current or recent users (<6 months since last use) and current users with longer duration of COC use *[seePostmarketing Experience (6.2)].*

Cervical Cancer

Some studies suggest that COCs are associated with an increase in the risk of cervical cancer or intraepithelial neoplasia. However, there is controversy about the extent to which these findings are due to differences in sexual behavior and other factors.

5.3 Liver Disease

Discontinue Jaimiess if jaundice develops. Steroid hormones may be poorly metabolized in patients with impaired liver function. Acute or chronic disturbances of liver function may necessitate the discontinuation of COC use until markers of liver function return to normal and COC causation has been excluded.

Hepatic adenomas are associated with COC use. An estimate of the attributable risk is 3.3 cases/100,000 COC users. Rupture of hepatic adenomas may cause death through intra-abdominal hemorrhage.

Studies have shown an increased risk of developing hepatocellular carcinoma in long-term (> 8 years) COC users. However, the attributable risk of liver cancers in COC users is less than one case per million users.

Oral contraceptive-related cholestasis may occur in women with a history of pregnancy-related cholestasis. Women with a history of COC-related cholestasis may have the condition recur with subsequent COC use.

5.4 Risk of Liver Enzyme Elevations with Concomitant Hepatitis C Treatment

During clinical trials with the Hepatitis C combination drug regimen that containsobmitasvir/paritaprevir/ritonavir, with or without dasabuvir, ALT elevations greater than 5 times the upper limit of normal (ULN), including some cases greater than 20 times the ULN, were significantly more frequent in women using ethinyl estradiol-containing medications, such as COCs. Discontinue Jaimiess prior to starting therapy

with the combination drug regimen ombitasvir/paritaprevir/ritonavir, with or without dasabuvir [see **CONTRAINDICATIONS (4)]**.Jaimiess can be restarted approximately 2 weeks following completion of treatment with the Hepatitis C combination drug regimen.

5.5 High Blood Pressure

For women with well-controlled hypertension, monitor blood pressure and stop Jaimiess if blood pressure rises significantly. Women with uncontrolled hypertension or hypertension with vascular disease should not use COCs.

An increase in blood pressure has been reported in women taking COCs, and this increase is more likely in older women and with extended duration of use. The incidence of hypertension increases with increasing concentration of progestin.

5.6 Gallbladder Disease

Studies suggest a small increased relative risk of developing gallbladder disease among COC users.

5.7 Carbohydrate and Lipid Metabolic Effects

Carefully monitor prediabetic and diabetic women who are taking Jaimiess. COCs may decrease glucose tolerance in a dose-related fashion.

Consider alternative contraception for women with uncontrolled dyslipidemias. A small proportion of women will have adverse lipid changes while on COCs.

Women with hypertriglyceridemia, or a family history thereof, may be at an increased risk of pancreatitis when using COCs.

5.8 Headache

If a woman taking Jaimiess develops new headaches that are recurrent, persistent, or severe, evaluate the cause and discontinue Jaimiess if indicated.

An increase in frequency or severity of migraine during COC use (which may be prodromal of a cerebrovascular event) may be a reason for immediate discontinuation of the COC.

5.9 Bleeding Irregularities

Unscheduled (breakthrough) bleeding and spotting sometimes occur in patients on COCs, especially during the first 3 months of use. If bleeding persists, check for causes such as pregnancy or malignancy. If pathology and pregnancy are excluded, bleeding irregularities may resolve over time or with a change to a different COC.

When prescribing Jaimiess, the convenience of fewer planned menses (4 per year instead of 13 per year) should be weighed against the inconvenience of increased unscheduled bleeding and/or spotting. The primary clinical trial (PSE-301) that evaluated the efficacy of levonorgestrel and ethinyl estradiol tablets, and ethinyl estradiol tablets also assessed unscheduled bleeding. The participants in the 12-month clinical trial (N=1,006) completed the equivalent of 8,681 28-day cycles of exposure and were composed primarily of women who had used oral contraceptives previously (89%) as opposed to new users (11%). A total of 82 (8.2%) of the women discontinued levonorgestrel and ethinyl estradiol tablets, and ethinyl estradiol tablets, at

least in part, due to bleeding or spotting.

Scheduled (withdrawal) bleeding and/or spotting remained fairly constant over time, with an average of 3 days of bleeding and/or spotting per each 91-day cycle. Unscheduled bleeding and unscheduled spotting decreased over successive 91-day cycles. **Table 1** below presents the number of days with unscheduled bleeding in treatment cycles 1 and 4. **Table 2** presents the number of days with unscheduled spotting in treatment cycles 1 and 4.

Table 1 Total Number of Days with Unscheduled Bleeding

91-Day Treatment Cycle	Days per 84-Day Interval				Days per 28-Day Interval
	Q1	Median	Q3	Mean	Mean
1st	1	4	10	6.9	1.7
4th	0	1	4	3.2	0.8

Q1=Quartile 1: 25% of women had this number of days of unscheduled bleeding
Median: 50% of women had ≤ this number of days of unscheduled bleeding
Q3=Quartile 3: 75% of women had ≤ this number of days of unscheduled bleeding

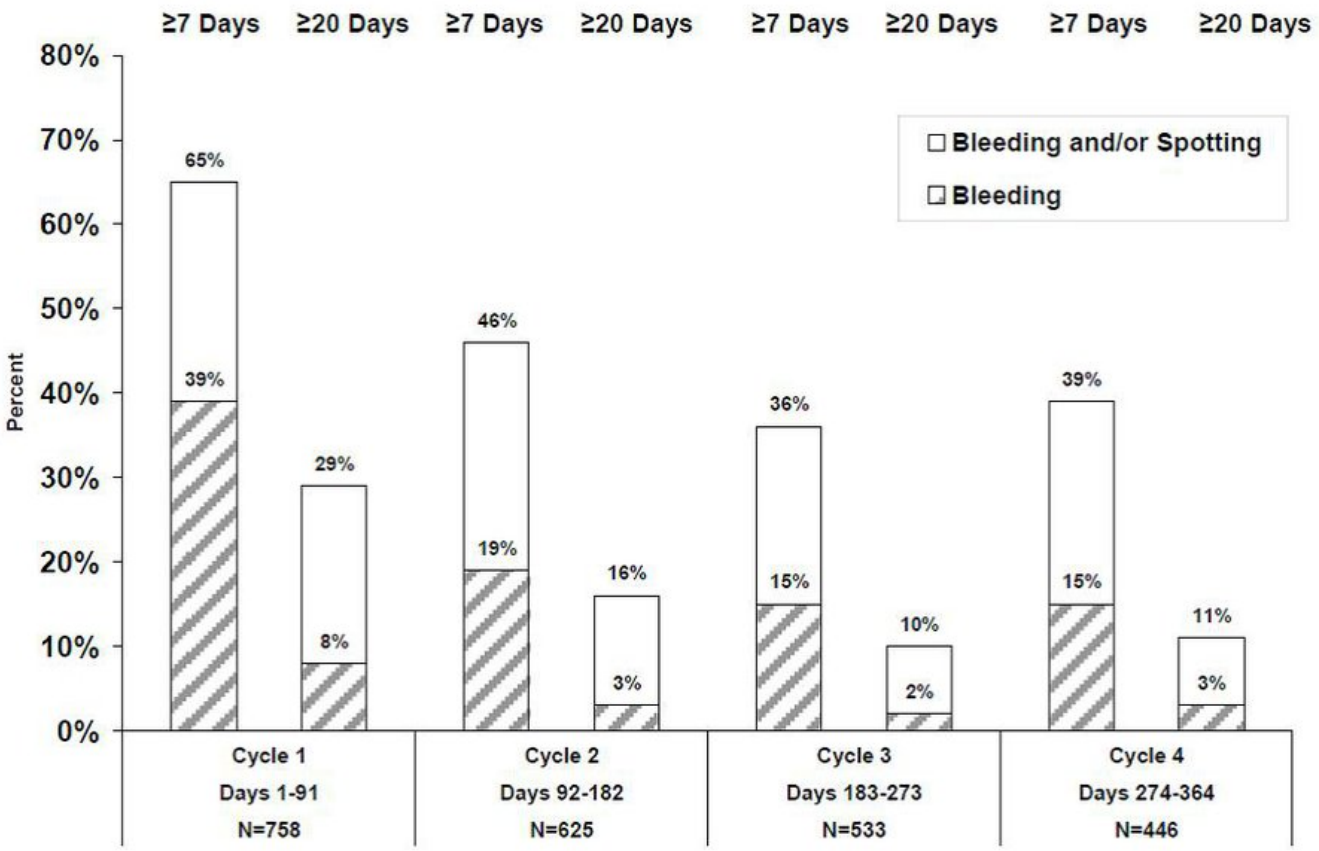
Table 2 Total Number of Days with Unscheduled Spotting

91-Day Treatment Cycle	Days per 84-Day Interval				Days per 28-Day Interval
	Q1	Median	Q3	Mean	Mean
1st	1	4	11	7.4	1.9
4th	0	2	7	4.4	1.1

Q1=Quartile 1: 25% of women had ≤ this number of days of unscheduled spotting
Median: 50% of women had ≤ this number of days of unscheduled spotting
Q3=Quartile 3: 75% of women had ≤ this number of days of unscheduled spotting.

Figure 1 shows the percentage of levonorgestrel and ethinyl estradiol tablets, and ethinyl estradiol tablets subjects participating in trial PSE-301 with ≥ 7 days or ≥ 20 days of unscheduled bleeding and/or spotting, or only unscheduled bleeding, during each 91-day treatment cycle.

Figure 1 Percent of Women Taking Levonorgestrel and Ethinyl Estradiol Tablets, and Ethinyl Estradiol Tablets who Reported Unscheduled Bleeding and/or Spotting or only Unscheduled Bleeding



Amenorrhea sometimes occurs in women who are using COCs. Pregnancy should be ruled out in the event of amenorrhea. Some women may encounter amenorrhea or oligomenorrhea after stopping COCs, especially when such a condition was pre-existent.

5.10 COC Use Before and During Early Pregnancy

Extensive epidemiological studies have revealed no increased risk of birth defects in women who have used oral contraceptives prior to pregnancy. Studies also do not suggest a teratogenic effect, particularly in so far as cardiac anomalies and limb-reduction defects are concerned, when taken inadvertently during early pregnancy. Oral contraceptive use should be discontinued if pregnancy is confirmed.

The administration of oral contraceptives to induce withdrawal bleeding should not be used as a test for pregnancy [see **USE IN SPECIFIC POPULATIONS (8.1)].**

5.11 Emotional Disorders

Women with a history of depression should be carefully observed and Jaimiess discontinued if depression recurs to a serious degree.

5.12 Interference with Laboratory Tests

The use of COCs may change the results of some laboratory tests, such as coagulation factors, lipids, glucose tolerance, and binding proteins. Women on thyroid hormone replacement therapy may need increased doses of thyroid hormone because serum

concentrations of thyroid binding globulin increase with use of COCs.

5.13 Monitoring

A woman who is taking COCs should have a yearly visit with her healthcare provider for a blood pressure check and for other indicated health care.

5.14 Other Conditions

In women with hereditary angioedema, exogenous estrogens may induce or exacerbate symptoms of angioedema. Chloasma may occasionally occur, especially in women with a history of chloasma gravidarum. Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation while taking COCs.

6 ADVERSE REACTIONS

The following serious adverse reactions with the use of COCs are discussed elsewhere in the labeling:

- Serious cardiovascular events and smoking [see **BOXED WARNING AND WARNINGS AND PRECAUTIONS (5.1)]**
- Vascular events [see **WARNINGS AND PRECAUTIONS (5.1)]**
- Liver disease [see **WARNINGS AND PRECAUTIONS (5.3)]**

Adverse reactions commonly reported by COC users are:

- Irregular uterine bleeding
- Nausea
- Breast tenderness
- Headache

6.1 Clinical Trial Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to the rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The clinical trial that evaluated the safety and efficacy of levonorgestrel and ethinyl estradiol tablets, and ethinyl estradiol tablets was a 12-month, randomized, multicenter, open-label study, which enrolled women aged 18 to 40, of whom 1,006 took at least one dose of levonorgestrel and ethinyl estradiol tablets, and ethinyl estradiol tablets.

Adverse Reactions Leading to Study Discontinuation

16.3% of the women discontinued from the clinical trial due to an adverse reaction; the most common adverse reactions (≥ 1% of women) leading to discontinuation were irregular and/or heavy uterine bleeding (5.9%), weight gain (2.4%), mood changes (1.5%), and acne (1.0%).

Common Treatment-Emergent Adverse Reactions (≥ 5% of women)

Irregular and/or heavy uterine bleeding (17%), weight gain (5%), acne (5%).

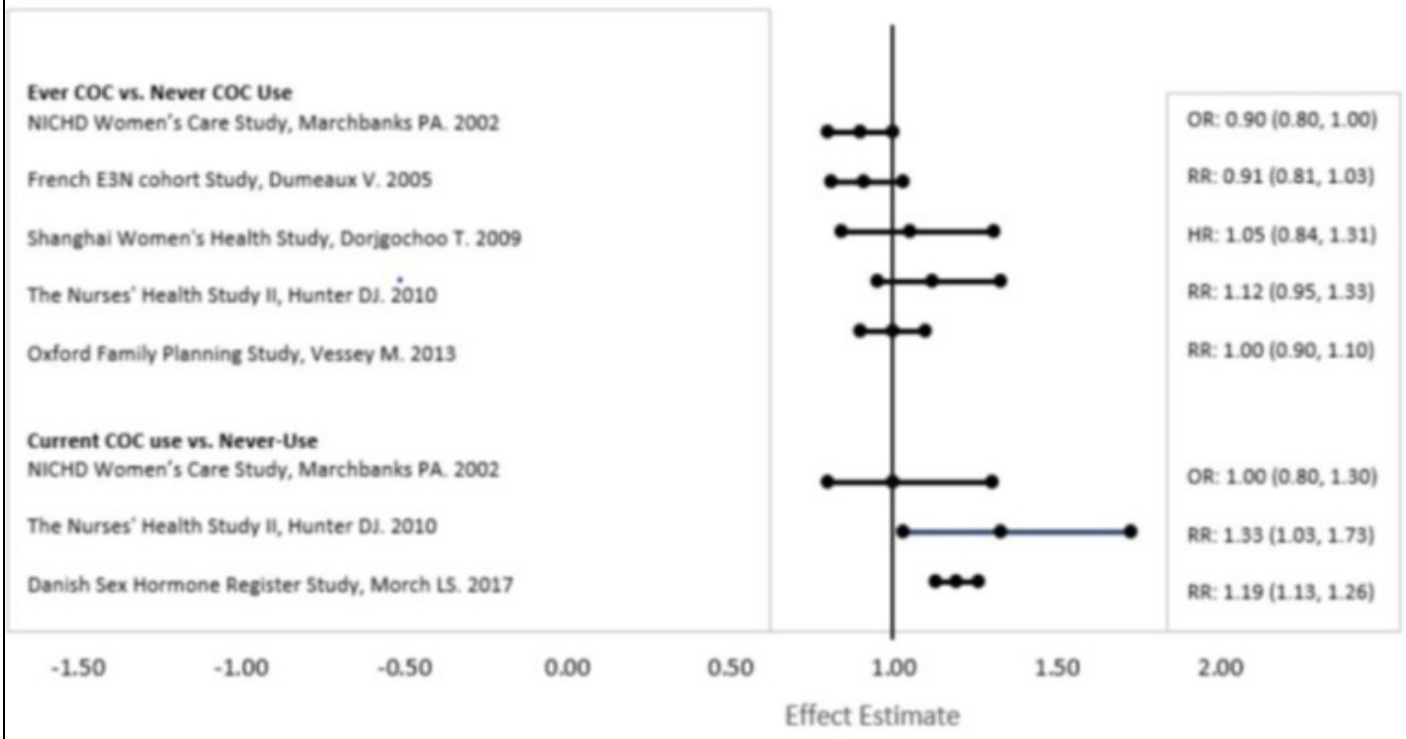
Serious Adverse Reactions

Migraine, cholecystitis, cholelithiasis, pancreatitis, abdominal pain, and major depressive disorder.

6.2 Postmarketing Experience

Five studies that compared breast cancer risk between ever-users (current or past use) of COCs and never-users of COCs reported no association between ever use of COCs and breast cancer risk, with effect estimates ranging from 0.90 - 1.12 (Figure 2). Three studies compared breast cancer risk between current or recent COC users (<6 months since last use) and never users of COCs (Figure 2). One of these studies reported no association between breast cancer risk and COC use. The other two studies found an increased relative risk of 1.19 - 1.33 with current or recent use. Both of these studies found an increased risk of breast cancer with current use of longer duration, with relative risks ranging from 1.03 with less than one year of COC use to approximately 1.4 with more than 8-10 years of COC use.

Figure 2 Relevant Studies of Risk of Breast Cancer with Combined Oral Contraceptives



RR = relative risk; OR = odds ratio; HR = hazard ratio. “ever COC” are females with current or past COC use; “never COC use” are females that never used COCs.

The following adverse reactions have been identified during post-approval use of levonorgestrel and ethinyl estradiol tablets, and ethinyl estradiol tablets. Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency of establish a causal relationship to drug exposure.

***Gastrointestinal disorders*:** abdominal distension, vomiting

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

***Immune system disorders*:** hypersensitivity reaction

Investigations: blood pressure increased

***Musculoskeletal and connective tissue disorders*:** muscle spasms, pain in extremity

***Nervous system disorders*:** dizziness, loss of consciousness

***Psychiatric disorders*:** insomnia

***Reproductive and breast disorders*:** dysmenorrhea

Respiratory, thoracic and mediastinal disorders: pulmonary embolism, pulmonary thrombosis

***Skin and subcutaneous tissue disorders*:** alopecia

***Vascular disorders*:** thrombosis

7 DRUG INTERACTIONS

No drug-drug interaction studies were conducted with Jaimiess.

7.1 Changes in Contraceptive Effectiveness Associated with Co-Administration of Other Products

If a woman on hormonal contraceptives takes a drug or herbal product that induces enzymes, including CYP3A4, that metabolize contraceptive hormones, counsel her to use additional contraception or a different method of contraception. Drugs or herbal products that induce such enzymes may decrease the plasma concentrations of contraceptive hormones, and may decrease the effectiveness of hormonal contraceptives or increase breakthrough bleeding. Some drugs or herbal products that may decrease the effectiveness of hormonal contraceptives include:

- barbiturates
- bosentan
- carbamazepine
- felbamate
- griseofulvin
- oxcarbazepine
- phenytoin
- rifampin
- St. John’s wort
- topiramate

HIV protease inhibitors and non-nucleoside reverse transcriptase inhibitors: Significant changes (increase or decrease) in the plasma levels of the estrogen and progestin have been noted in some cases of co-administration of HIV protease inhibitors or with non-nucleoside reverse transcriptase inhibitors.

Antibiotics: There have been reports of pregnancy while taking hormonal contraceptives and antibiotics, but clinical pharmacokinetic studies have not shown consistent effects of antibiotics on plasma concentrations of synthetic steroids.

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

7.2 Increase in Plasma Levels of Estradiol Associated with Co-Administered Drugs

Co-administration of atorvastatin and certain COCs containing ethinyl estradiol increase AUC values for ethinyl estradiol by approximately 20%. Ascorbic acid and acetaminophen may increase plasma ethinyl estradiol levels, possibly by inhibition of conjugation. CYP3A4 inhibitors such as itraconazole or ketoconazole may increase plasma hormone levels.

7.3 Concomitant Use with Hepatitis C Vaccine (HCV) Combination Therapy – Liver Enzyme Elevation

Do not co-administer Jaimiess with HCV drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, due to potential for ALT elevations [see **WARNINGS AND PRECAUTIONS (5.4)**].

7.4 Changes in Plasma Levels of Co-Administered Drugs

COCs containing some synthetic estrogens (e.g., ethinyl estradiol) may inhibit the metabolism of other compounds. COCs have been shown to significantly decrease plasma concentrations of lamotrigine likely due to induction of lamotrigine glucuronidation. This may reduce seizure control; therefore, dosage adjustments of lamotrigine may be necessary. Consult the labeling of the concurrently-used drug to obtain further information about interactions with COCs or the potential for enzyme alterations.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

There is little or no increased risk of birth defects in women who inadvertently use COCs during early pregnancy. Epidemiologic studies and meta-analyses have not found an increased risk of genital or non-genital birth defects (including cardiac anomalies and limb-reduction defects) following exposure to low dose COCs prior to conception or during early pregnancy.

The administration of COCs to induce withdrawal bleeding should not be used as a test for pregnancy. COCs should not be used during pregnancy to treat threatened or habitual abortion.

Women who do not breastfeed may start COCs no earlier than four to six weeks postpartum.

8.3 Nursing Mothers

When possible, advise the nursing mother to use other forms of contraception until she has weaned her child. Estrogen-containing COCs can reduce milk production in breastfeeding mothers. This is less likely to occur once breastfeeding is well established; however, it can occur at any time in some women. Small amounts of oral contraceptive steroids and/or metabolites are present in breast milk.

8.4 Pediatric Use

Safety and efficacy of Jaimiess have been established in women of reproductive age. Safety and efficacy are expected to be the same for postpubertal adolescents under the

age of 18 as for users 18 years and older. Use of Jaimiess before menarche is not indicated.

8.5 Geriatric Use

Jaimiess have not been studied in women who have reached menopause and is not indicated in this population.

8.6 Hepatic Impairment

No studies have been conducted to evaluate the effect of hepatic disease on the disposition of Jaimiess. However, steroid hormones may be poorly metabolized in patients with impaired liver function. Acute or chronic disturbances of liver function may necessitate the discontinuation of COC use until markers of liver function return to normal. [See **CONTRAINDICATIONS (4) and WARNINGS AND PRECAUTIONS (5.3)].**

8.7 Renal Impairment

No studies have been conducted to evaluate the effect of renal disease on the disposition of Jaimiess.

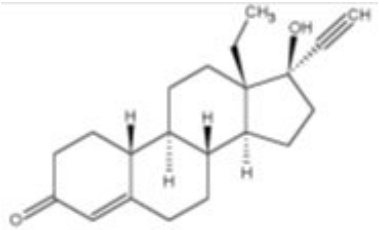
10 OVERDOSAGE

There have been no reports of serious ill effects from overdose of oral contraceptives, including ingestion by children. Overdosage may cause withdrawal bleeding in females and nausea.

11 DESCRIPTION

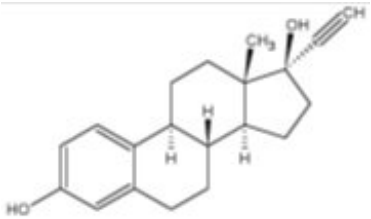
Jaimiess is an extended-cycle oral contraceptive consisting of 84 peach tablets each containing 0.15 mg of levonorgestrel, a synthetic progestogen and 0.03 mg of ethinyl estradiol, and 7 yellow tablets containing 0.01 mg of ethinyl estradiol.

The structural formulas for the active components are:



Levonorgestrel $C_{21}H_{28}O_2$ MW: 312.4

Levonorgestrel is chemically 18,19-Dinorpregn-4-en-20-yn-3-one, 13-ethyl-17-hydroxy-, (17α)-, (-)-.



Ethinyl Estradiol $C_{20}H_{24}O_2$ MW: 296.4

Ethinyl Estradiol is 19-Norpregna-1,3,5(10)-trien-20-yne-3,17-diol, (17α)-.

***Each peach tablet contains the following inactive ingredients*:** anhydrous lactose, iron oxide black, iron oxide red, iron oxide yellow, magnesium stearate, povidone, polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.

***Each yellow tablet contains the following inactive ingredients*:** iron oxide yellow, lactose monohydrate, lecithin, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, talc, titanium dioxide and xanthan gum.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

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

12.3 Pharmacokinetics

Absorption

Ethinyl estradiol and levonorgestrel are absorbed with maximum plasma concentrations occurring within 2 hours after levonorgestrel and ethinyl estradiol, and ethinyl estradiol administration.

Levonorgestrel is completely absorbed after oral administration (bioavailability nearly 100%) and is not subject to first-pass metabolism. Ethinyl estradiol is absorbed from the gastrointestinal tract but, due to first-pass metabolism in gut mucosa and liver, the bioavailability of ethinyl estradiol is approximately 43%.

The daily exposure to levonorgestrel and ethinyl estradiol on Day 21, corresponding to the end of a typical 3-week contraceptive regimen, and on Day 84, at the end of an extended cycle regimen, were similar. There was no additional accumulation of ethinyl estradiol after dosing a 0.03 mg ethinyl estradiol tablet during Days 84 to 91. The mean plasma pharmacokinetic parameters of levonorgestrel and ethinyl estradiol, and ethinyl estradiol following a single dose of one levonorgestrel and ethinyl estradiol combination tablet, for 84 days, in normal healthy women are reported in **Table 3**.

Table 3: Mean Pharmacokinetic Parameters for Levonorgestrel and Ethinyl Estradiol, and Ethinyl Estradiol During Daily One Tablet Dosing for 84 Days

	$AUC_{0\text{-}24\ hr}$	C_{max}	T_{max}

	(mean ± SD)	(mean ± SD)	(mean ± SD)
	Levonorgestrel		
Day 1	18.2 ± 6.1 ng•hr/mL	3.0 ± 1.0 ng/mL	1.3 ± 0.4 hours
Day 21	64.4 ± 25.1 ng•hr/mL	6.2 ± 1.6 ng/mL	1.3 ± 0.4 hours
Day 84	60.2 ± 24.6 ng•hr/mL	5.5 ± 1.6 ng/mL	1.3 ± 0.3 hours
	Ethinyl Estradiol		
Day 1	509.3 ± 172.0 pg•hr/mL	69.8 ± 26 pg/mL	1.5 ± 0.3 hours
Day 21	837.1 ± 271.2 pg•hr/mL	99.6 ± 31 pg/mL	1.5 ± 0.3 hours
Day 84	791.5 ± 215.0 pg•hr/mL	91.3 ± 32 pg/mL	1.6 ± 0.3 hours

The effect of food on the rate and the extent of levonorgestrel and ethinyl estradiol absorption following oral administration of Jaimiess has not been evaluated.

Distribution

The apparent volume of distribution of levonorgestrel and ethinyl estradiol are reported to be approximately 1.8 L/kg and 4.3 L/kg, respectively. Levonorgestrel is about 97.5 to 99% protein-bound, principally to sex hormone binding globulin (SHBG) and, to a lesser extent, serum albumin. Ethinyl estradiol is about 95 to 97% bound to serum albumin.

Ethinyl estradiol does not bind to SHBG, but induces SHBG synthesis, which leads to decreased levonorgestrel clearance. Following repeated daily dosing of levonorgestrel and ethinyl estradiol oral contraceptives, levonorgestrel plasma concentrations accumulate more than predicted based on single-dose pharmacokinetics, due in part, to increased SHBG levels that are induced by ethinyl estradiol, and a possible reduction in hepatic metabolic capacity.

Metabolism

Following absorption, levonorgestrel is conjugated at the 17β-OH position to form sulfate and to a lesser extent, glucuronide conjugates in plasma. Significant amounts of conjugated and unconjugated 3α,5β-tetrahydrolevonorgestrel are also present in plasma, along with much smaller amounts of 3α,5α-tetrahydrolevonorgestrel and 16β-hydroxylevonorgestrel. Levonorgestrel and its phase I metabolites are excreted primarily as glucuronide conjugates. Metabolic clearance rates may differ among individuals by several-fold, and this may account in part for the wide variation observed in levonorgestrel concentrations among users.

First-pass metabolism of ethinyl estradiol involves formation of ethinyl estradiol-3-sulfate in the gut wall, followed by 2-hydroxylation of a portion of the remaining untransformed ethinyl estradiol by hepatic cytochrome P-450 3A4 (CYP3A4). Levels of CYP3A4 vary widely among individuals and can explain the variation in rates of ethinyl estradiol hydroxylation. Hydroxylation at the 4-, 6-, and 16- positions may also occur, although to a much lesser extent than 2-hydroxylation. The various hydroxylated metabolites are subject to further methylation and/or conjugation.

Excretion

About 45% of levonorgestrel and its metabolites are excreted in the urine and about 32% are excreted in feces, mostly as glucuronide conjugates. The terminal elimination half-life for levonorgestrel after a single dose of levonorgestrel and ethinyl estradiol and ethinyl estradiol was about 34 hours.

Ethinyl estradiol is excreted in the urine and feces as glucuronide and sulfate conjugates, and it undergoes enterohepatic recirculation. The terminal elimination half-life of ethinyl estradiol after a single dose of levonorgestrel and ethinyl estradiol, and ethinyl estradiol was found to be about 18 hours.

Race

The effect of race on the pharmacokinetics of Jaimiess has not been evaluated.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

[See **WARNINGS AND PRECAUTIONS** (5.2, 5.3)].

14 CLINICAL STUDIES

In a 12-month, multicenter, randomized, open-label clinical trial, 1,006 women aged 18 to 40 were studied to assess the safety and efficacy of levonorgestrel and ethinyl estradiol, and ethinyl estardiol, completing the equivalent of 8,681 28-day cycles of exposure. The racial demographic of those enrolled was: Caucasian (80%), African-American (11%), Hispanic (5%), Asian (2%), and Other (2%). There were no exclusions for body mass index (BMI) or weight.

The weight range of those women treated was 91 to 360 lbs., with a mean weight of 156 lbs. Among the women in the trial, 63% were current or recent hormonal contraceptive users, 26% were prior users (who had used hormonal contraceptives in the past but not in the 6 months prior to enrollment), and 11% were new starts. Of treated women, 14.8% were lost to follow-up, 16.3% discontinued due to an adverse event, and 12.9% discontinued by withdrawing their consent.

The pregnancy rate (Pearl Index [PI]) in women aged 18 to 35 years was 1.34 pregnancies per 100 women-years of use (95% confidence interval 0.54-2.75), based on 7 pregnancies that occurred after the onset of treatment and within 14 days after the last combination pill. Cycles in which conception did not occur, but which included the use of backup contraception, were not included in the calculation of the PI. The PI includes patients who did not take the drug correctly.

16 HOW SUPPLIED/STORAGE AND HANDLING

Jaimiess (levonorgestrel/ethinyl estradiol tablets, USP and ethinyl estradiol tablets, USP) are available in Extended-Cycle Tablet Dispensers, each containing a 13-week supply of tablets: 84 peach tablets, each containing 0.15 mg of levonorgestrel and 0.03 mg ethinyl estradiol, and 7 yellow tablets each containing 0.01 mg of ethinyl estradiol. The peach tablets are round, film-coated, debossed with SZ on one side and J4 on the other side. The yellow tablets are round, film-coated, debossed with SZ on one side and L1 on the other side.

NDC 63629-2345-01 (1 extended-cycle tablet dispenser, each tablet dispenser contains 91 tablets)

Repackaged/Relabeled by:

Bryant Ranch Prepack, Inc.

Burbank, CA 91504

17 PATIENT COUNSELING INFORMATION

See FDA- Approved Patient Labeling

- Counsel patients that cigarette smoking increases the risk of serious cardiovascular events from COC use, and that women who are over 35 years old and smoke should not use COCs.
- Counsel patients that this product does not protect against HIV-infection (AIDS) and other sexually transmitted diseases.
- Counsel patients on Warnings and Precautions associated with COCs.
- Counsel patients to take one tablet daily by mouth at the same time every day. Instruct patients what to do in the event pills are missed. See **WHAT TO DO IF YOU MISS PILLS** section of FDA-Approved Patient Labeling.
- Counsel patients to use a back-up or alternative method of contraception when enzyme inducers are used with COCs.
- Counsel patients who are breastfeeding or who desire to breastfeed that COCs may reduce breast milk production. This is less likely to occur if breastfeeding is well established.
- Counsel any patient who starts COCs postpartum, and who has not yet had a period, to use an additional method of contraception until she has taken a peach tablet for 7 consecutive days.
- Counsel patients that amenorrhea may occur. Pregnancy should be considered in the event of amenorrhea, and should be ruled out if amenorrhea is associated with symptoms of pregnancy, such as morning sickness or unusual breast tenderness.

Manufactured by Laboratorios Leon Farma S.A., Spain
For Xiromed, LLC, Florham Park, NJ 07932

Product of Spain

Rev. 06/2022

PI-123-03

FDA-Approved Patient Labeling

Jaimiess®
Levonorgestrel and Ethinyl Estradiol Tablets, USP and Ethinyl Estradiol Tablets, USP
0.15 mg/0.03 mg and 0.01 mg

for oral use
Initial U.S. Approval: 1982

WARNING TO WOMEN WHO SMOKE

Do not use Jaimiess if you smoke cigarettes and are over 35 years old. Smoking increases your risk of serious cardiovascular side effects from birth

control pills, including death from heart attack, blood clots or stroke. This risk increases with age and the number of cigarettes you smoke.

Birth control pills help to lower the chances of becoming pregnant. They do not protect against HIV infection (AIDS) and other sexually transmitted diseases.

What is Jaimiess?

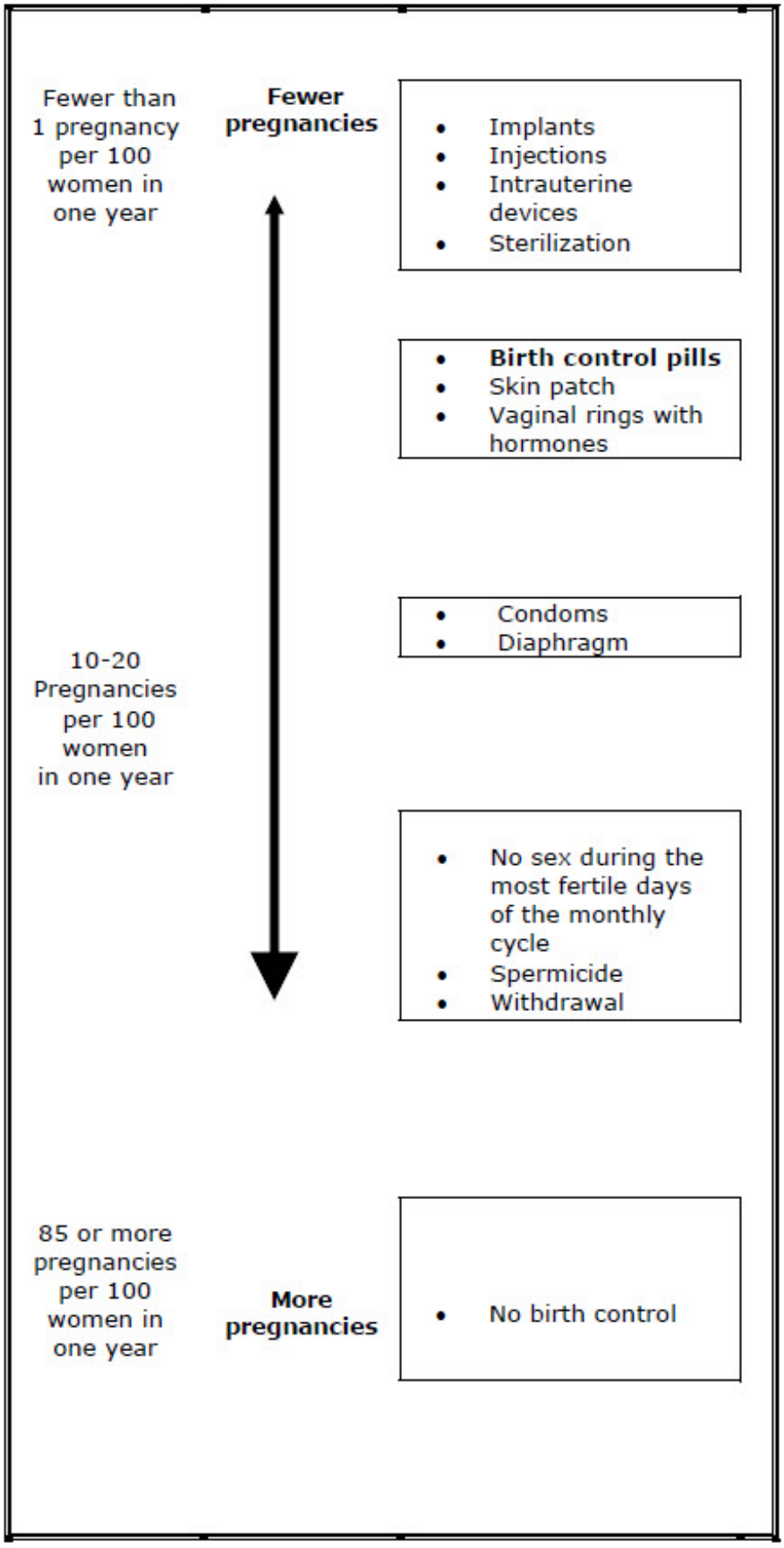
Jaimiess is a birth control pill. It contains two female hormones, an estrogen called ethinyl estradiol, and a progestin called levonorgestrel.

How Well Does Jaimiess Work?

Your chance of getting pregnant depends on how well you follow the directions for taking your birth control pills. The more carefully you follow the directions, the less chance you have of getting pregnant.

Based on the results of a single clinical study lasting 12 months, 1 to 3 women, out of 100 women, may get pregnant during the first year they use Jaimiess.

The following chart shows the chance of getting pregnant for women who use different methods of birth control. Each box on the chart contains a list of birth control methods that are similar in effectiveness. The most effective methods are at the top of the chart. The box on the bottom of the chart shows the chance of getting pregnant for women who do not use birth control and are trying to get pregnant.



How Do I Take Jaimiess?

1.Take one pill every day at the same time. If you miss pills you could get pregnant. This

includes starting the pack late. The more pills you miss, the more likely you are to get pregnant.

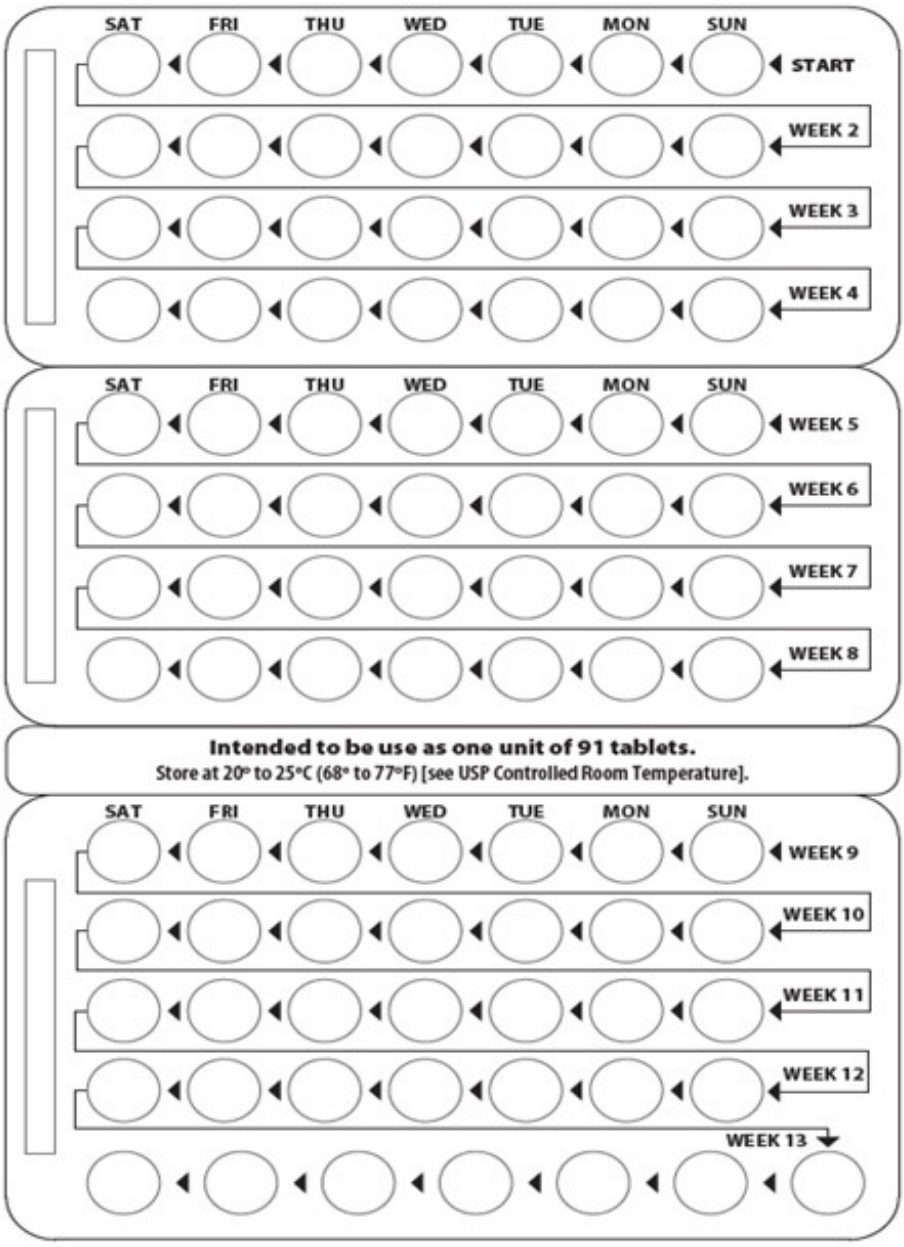
2.Many women have spotting or light bleeding, or may feel sick to their stomach during the first few months of taking Jaimiess. If you feel sick to your stomach, do not stop taking the pill. The problem will usually go away. If it doesn't go away, check with your healthcare provider.

3.Missing pills can also cause spotting or light bleeding, even when you take the missed pills later. On the days you take 2 pills to make up for missed pills, you could also feel a little sick to your stomach.

4.If you have trouble remembering to take Jaimiess, talk to your healthcare provider about how to make pill-taking easier or about using another method of birth control.

Before You Start Taking Jaimiess

1. Decide what time of day you want to take your pill. It is important to take it at about the same time every day.
2. Look at your Extended-Cycle Tablet Dispenser. Your Tablet Dispenser consists of a Tri-Fold Blister card that hold 91 individually sealed pills (a 13-week or 91-day cycle). The 91 pills consist of 84 peach and 7 yellow pills. The first two blister card sections each contain 28 peach pills (4 rows of 7 pills). The third blister card section contains 35 pills consisting of 28 peach pills (4 rows of 7 pills) and 7 yellow pills (1 row of 7 pills).



3. Also find:
   - Where on the first blister card in the pack to start taking pills (upper left corner at the start arrow) and
   - In what order to take the pills (follow the weeks and arrow).
4. Be sure you have ready at all times another kind of birth control (such as condoms or spermicides), to use as a back-up in case you miss pills.

When To Start Jaimiess

1. Take the first peach pill on the Sunday after your period starts, even if you are still bleeding. If your period begins on Sunday, start the first peach pill that same day.
2. Use another method of birth control (such as condoms or spermicides) as a back-up method if you have sex anytime from the Sunday you start your first peach pill until the next Sunday (first 7 days). If you have been using a different hormonal method of birth control (such as a different pill, the “patch,” or the “vaginal ring”), you need to use another method of birth control (such as condoms or spermicides) each time you have sex after stopping your old method of birth control until you have taken

Jaimiess for 7 days.

How To Take Jaimiess

1. Take one pill at the same time every day until you have taken the last pill in the tablet dispenser.
   - Do not skip pills even if you are experiencing spotting or bleeding or feel sick to your stomach (nausea).
   - Do not skip pills even if you do not have sex very often.
2. **When you finish a tablet dispenser**
   - After taking the last yellow pill, start taking the first peach pill from a new Extended-Cycle Tablet Dispenser the very next day (this should be on a Sunday) regardless of when your period started.
3. If you miss your scheduled period when you are taking the yellow pills, contact your healthcare provider because you may be pregnant. If you are pregnant, you should stop taking Jaimiess.

What To Do If You Miss Pills

If you **MISS 1** peach pill:

1. Take it as soon as you remember. Take the next pill at your regular time. This means you may take 2 pills in 1 day.
2. You do not need to use a back-up birth control method if you have sex.

If you **MISS 2** peach pills in a row:

1. Take 2 pills on the day you remember, and 2 pills the next day.
2. Then take 1 pill a day until you finish the pack.
3. You could become pregnant if you have sex in the 7 days after you miss two pills. You MUST use another birth control method (such as condoms or spermicide) as a back up for the 7 days after you restart your pills.

If you **MISS 3 OR MORE** peach pills in a row:

1. Do not take the missed pills. Keep taking 1 pill every day as indicated on the pack until you have completed all of the remaining pills in the pack. For example: If you resume taking the pill on Thursday, take the pill under “Thursday” and do not take the missed pills. You may experience bleeding during the week following the missed pills.
2. You could become pregnant if you have sex during the days of missed pills or during the first 7 days after restarting your pills.
3. You MUST use a non-hormonal birth control method (such as condoms 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 yellow pills, call your healthcare provider because you may be pregnant.

If you **MISS ANY** of the 7 yellow pills:

1. Throw away the missed pills.
2. Keep taking the scheduled pills until the pack is finished.
3. You do not need a back-up method of birth control.

Finally, if you are still not sure what to do about the pills you have missed

1. Use a back-up method anytime you have sex.
2. Keep taking one pill each day until you contact your healthcare provider.

Who Should Not Take Jaimiess?

Your healthcare provider will not give you Jaimiess if you have:

- Ever had breast cancer or any cancer that is sensitive to female hormones
- Liver disease, including liver tumors
- Been prescribed any Hepatitis C drug combination containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir. This may increase levels of the liver enzyme “alanine aminotransferase” (ALT) in the blood
- Ever had blood clots in your arms, legs, or lungs
- Ever had a stroke
- Ever had a heart attack
- Certain heart valve problems or heart rhythm abnormalities that can cause blood clots to form in the heart
- An inherited problem with your blood that makes it clot more than normal High blood pressure that medicine can't control
- Diabetes with kidney, eye, or blood vessel damage
- Certain kinds of severe migraine headaches with aura, numbness, weakness or changes in vision

Also, do not take birth control pills if you:

- Smoke and are over 35 years old
- Are pregnant

Birth control pills may not be a good choice for you if you have ever had jaundice (yellowing of the skin or eyes) caused by pregnancy.

What Else Should I Know About Taking Jaimiess?

Birth control pills do **not** protect you against any sexually transmitted disease, including HIV, the virus that causes AIDS.

Do not skip any pills, even if you do not have sex often.

Birth control pills should not be taken during pregnancy. However, birth control pills taken by accident during pregnancy are not known to cause birth defects.

If you are breastfeeding, consider another birth control method until you are ready to stop breastfeeding. Birth control pills that contain estrogen, like Jaimiess, may decrease the amount of milk you make. A small amount of the pill's hormones pass into breast milk.

Tell your healthcare provider about all medicines and herbal products that you take. Some medicines and herbal products may make birth control pills less effective, including:

- barbiturates
- bosentan
- carbamazepine
- felbamate
- griseofulvin
- oxcarbazepine
- phenytoin
- rifampin

- St. John’s wort
- topiramate

Consider using another birth control method when you take medicines that may make birth control pills less effective.

Birth control pills may interact with lamotrigine, an anticonvulsant used for epilepsy. This may increase the risk of seizures, so your physician may need to adjust the dose of lamotrigine.

If you have vomiting or diarrhea, your birth control pills may not work as well. Use another birth control method, like condoms or a spermicide, until you check with your healthcare provider.

What Are The Most Serious Risks Of Taking Birth Control Pills?

Like pregnancy, birth control pills increase the risk of serious blood clots, especially in women who have other risk factors, such as smoking, obesity, or age > 35. It is possible to die from a problem caused by a blood clot, such as a heart attack or a stroke. Some examples of serious blood clots are blood clots in the:
- Legs (thrombophlebitis)
- Lungs (pulmonary embolus)
- Eyes (loss of eyesight)
- Heart (heart attack)
- Brain (stroke)

Women who take birth control pills may get:
- High blood pressure
- Gallbladder problems
- Rare cancerous or noncancerous liver tumors

All of these events are uncommon in healthy women.

Call your healthcare provider right away if you have:
- Persistent leg pain
- Sudden shortness of breath
- Sudden blindness, partial or complete
- Severe pain in your chest
- Sudden, severe headache unlike your usual headaches
- Weakness or numbness in an arm or leg, or trouble speaking
- Yellowing of the skin or eyeballs

What Are Common Side Effects Of Birth Control Pills?

The most common side effects of birth control pills are:
- Spotting or bleeding between menstrual periods
- Nausea
- Breast tenderness
- Headache

These side effects are usually mild and usually disappear with time.

Less common side effects are:

- Acne
- Less sexual desire
- Bloating or fluid retention
- Blotchy darkening of the skin, especially on the face
- High blood sugar, especially in women who already have diabetes
- High fat levels in the blood
- Depression, especially if you have had depression in the past. Call your healthcare provider immediately if you have any thoughts of harming yourself.
- Problems tolerating contact lenses
- Weight changes

This is not a complete list of possible side effects. Talk to your healthcare provider if you develop any side effects that concern you. You may report side effects to the FDA at 1-800-FDA-1088.

No serious problems have been reported from a birth control pill overdose, even when accidentally taken by children.

Do Birth Control Pills Cause Cancer?

It is not known if hormonal birth control pills cause breast cancer. Some studies, but not all, suggest that there could be a slight increase in the risk of breast cancer among current users with longer duration of use.

If you have breast cancer now, or have had it in the past, do not use hormonal birth control because some breast cancers are sensitive to hormones.

Women who use birth control pills may have a slightly higher chance of getting cervical cancer. However, this may be due to other reasons such as having more sexual partners.

What Should I Know About My Period When Taking Jaimiess?

When you take Jaimiess, which has a 91-day extended dosing cycle, you should expect to have 4 scheduled periods per year (bleeding when you are taking the 7 yellow pills). Each period is likely to last about 3 days. However, you will probably have more bleeding or spotting between your scheduled periods than if you were using a birth control pill with a 28-day dosing cycle. During the first Jaimiess 91-day treatment cycle, about 3 in 10 women may have 20 or more days of unplanned bleeding or spotting. This bleeding or spotting tends to decrease with time. Do not stop taking Jaimiess because of this bleeding or spotting. If the spotting continues for more than 7 consecutive days or if the bleeding is heavy, call your healthcare provider.

What If I Miss My Scheduled Period When Taking Jaimiess?

You should consider the possibility that you are pregnant if you miss your scheduled period (no bleeding on the days that you are taking yellow tablets). Since scheduled periods are less frequent when you are taking Jaimiess, notify your healthcare provider that you have missed your period and that you are taking Jaimiess. Also notify your healthcare provider if you have symptoms of pregnancy such as morning sickness or unusual breast tenderness. It is important that your healthcare provider evaluates you to determine if you are pregnant. Stop taking Jaimiess if it is determined that you are pregnant.

What If I Want To Become Pregnant?

You may stop taking the pill whenever you wish. Consider a visit with your healthcare provider for a pre-pregnancy checkup before you stop taking the pill.

General Advice About Jaimiess

Your healthcare provider prescribed Jaimiess for you. Do not share Jaimiess with anyone else. Keep Jaimiess out of the reach of children.

If you have concerns or questions, ask your healthcare provider. You may also ask your healthcare providers for a more detailed label written for medical professionals.

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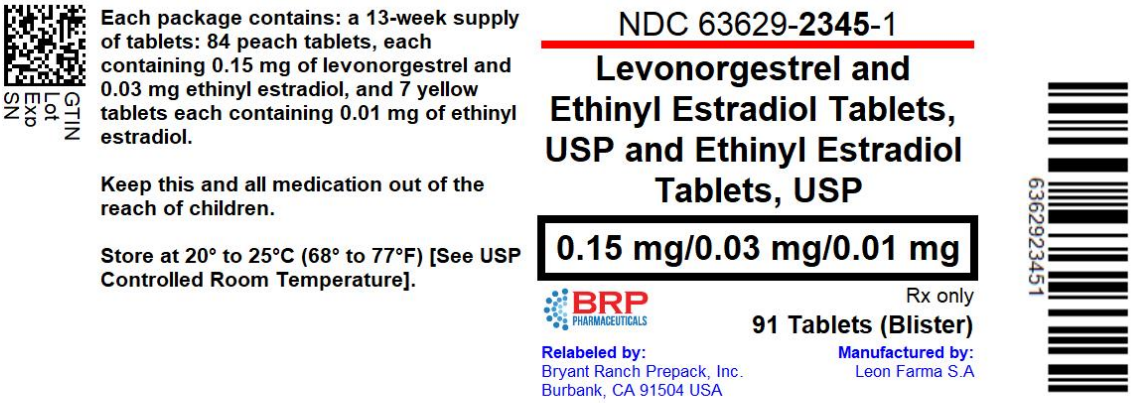
Manufactured by Laboratorios Leon Farma S.A., Spain

For Xiromed, LLC, Florham Park, NJ 07932

Product of Spain

Rev. 06/2022
PI-123-03

Levonorgestrel/Ethinyl Estradiol Tab, #91



JAIMIESS

levonorgestrel / ethinyl estradiol and ethinyl estradiol kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63629-2345(NDC:70700-123)

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63629-2345-1	1 in 1 BOX	01/01/2018	

1		1 in 1 BLISTER PACK		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1		84
Part 2		7

Part 1 of 2

LEVONORGESTREL/ETHINYL ESTRADIOL AND ETHINYL ESTRADIOL

levonorgestrel / ethinyl estradiol and ethinyl estradiol tablet, film coated

Product Information	
Item Code (Source)	NDC:70700-819
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LEVONORGESTREL (UNII: 5W7SIA7YZW) (LEVONORGESTREL - UNII:5W7SIA7YZW)	LEVONORGESTREL	0.15 mg
ETHINYL ESTRADIOL (UNII: 423D2T571U) (ETHINYL ESTRADIOL - UNII:423D2T571U)	ETHINYL ESTRADIOL	0.03 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE K30 (UNII: U725QWY32X)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	BROWN (peach)	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	SZ;J4
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203770	01/01/2018	

Part 2 of 2

LEVONORGESTREL/ETHINYL ESTRADIOL AND ETHINYL ESTRADIOL

levonorgestrel / ethinyl estradiol and ethinyl estradiol tablet, film coated

Product Information

Item Code (Source)	NDC:70700-820
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ETHINYL ESTRADIOL (UNII: 423D2T571U) (ETHINYL ESTRADIOL - UNII:423D2T571U)	ETHINYL ESTRADIOL	0.01 mg

Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	YELLOW	**Score**	no score
Shape	ROUND	**Size**	5mm
Flavor		**Imprint Code**	SZ;L1
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203770	01/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203770	01/01/2018	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(63629-2345) , RELABEL(63629-2345)

Revised: 1/2024