



TriLo-Marzia Tablets are available in 3 boxes. Each blister contains 28 tablets in the following order:

- 7 white, flat, round, film-coated tablets debossed with LU on one side and "E21" on the other side of the tablet contains 0.18 mg norgestimate and 0.025 mg ethinyl estradiol
- 7 light blue, round, film-coated tablets debossed with LU on one side and "E22" on the other side of the tablet contains 0.215 mg norgestimate and 0.025 mg ethinyl estradiol
- 7 blue, round, film-coated tablets debossed with LU on one side and "E23" on the other side of the tablet contains 0.23 mg norgestimate and 0.025 mg ethinyl estradiol
- 7 green, round, scoreless, film-coated tablets debossed with LU on one side and "E24" on the other side of the tablet contains inert ingredients

#### 4 CONTRAINDICATIONS

TriLo-Marzia is contraindicated in females who are known to have or develop the following conditions:

- A high risk of arterial or venous thrombotic disease. 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 an inherited or acquired hypercoagulopathy [see **WARNINGS AND PRECAUTIONS** (5.1)]
  - Have cardiovascular disease [see **WARNINGS AND PRECAUTIONS** (5.1)]
  - Have coronary artery disease [see **WARNINGS AND PRECAUTIONS** (5.1)]
  - Have thrombotic valvular or thrombotic rhythm diseases of the heart (for example, subacute bacterial endocarditis with valvular disease, or atrial fibrillation) [see **WARNINGS AND PRECAUTIONS** (5.1)]
  - Have uncontrolled hypertension [see **WARNINGS AND PRECAUTIONS** (5.4)]
  - Have diabetes mellitus with vascular disease [see **WARNINGS AND PRECAUTIONS** (5.6)]
  - Have headaches with focal neurological symptoms or migraine headaches with aura [see **WARNINGS AND PRECAUTIONS** (5.7)]
- Women over age 35 with any migraine headaches [see **WARNINGS AND PRECAUTIONS** (5.7)]
- Liver tumors, benign or malignant, or liver disease [see **WARNINGS AND PRECAUTIONS** (5.2)]
- Unexplained abnormal uterine bleeding [see **WARNINGS AND PRECAUTIONS** (5.8)]
- Pregnancy, because there is no reason to use COCs during pregnancy [see **WARNINGS AND PRECAUTIONS** (4.0) and **USE IN SPECIFIC POPULATIONS** (8.1)]
- Current diagnosis of, or history of, breast cancer, which may be hormone-sensitive [see **WARNINGS AND PRECAUTIONS** (5.1)]
- Use of Hepatitis C drug combinations containing ombitasvir/paritapavir/sofosbuvir, with or without daclatasvir, due to the potential for ALT elevations [see **WARNINGS AND PRECAUTIONS** (5.3)]

#### 5 WARNINGS AND PRECAUTIONS

##### 5.1 Thrombotic Disorders and Other Vascular Problems

- Stop TriLo-Marzia if an arterial thrombotic event or venous thrombotic (VTE) event occurs.
- Stop TriLo-Marzia if there is unexplained loss of vision, proptosis, diplopia, papilloedema, or retinal vascular lesions. Evaluate for retinal vein thrombosis immediately [see **ADVERSE REACTIONS** (6.2)].
- If feasible, stop TriLo-Marzia at least 4 weeks before and through 2 weeks after major surgery or other surgeries known to have an elevated risk of VTE as well as during the period of immobilization.
- Start TriLo-Marzia no earlier than 4 weeks after delivery, in women who are not breastfeeding. The risk of pulmonary VTE decreases after the third postpartum week, whereas the risk of venous thrombosis increases after the third postpartum week.
- The use of COCs increases the risk of VTE; however, pregnancy increases the risk of VTE as much or more than the use of COCs. The risk of VTE in women using COCs is 3 to 9 cases per 10,000 woman-years. The risk of VTE is highest during the first year of use of COCs and when restarting hormonal contraception after a break of 4 weeks or longer. The risk of thrombotic disease due to COCs gradually disappears after use is discontinued.
- Use of COCs also increases the risk of arterial thrombooses such as strokes and myocardial infarctions, especially in women with other risk factors for these events. COCs have been shown to increase both the relative and absolute risk of stroke and myocardial events (myocardial infarction and hemorrhagic stroke). This risk increases with age, particularly in women over 35 years of age who smoke.
- Use COCs with caution in women with cardiovascular disease risk factors.

##### 5.2 Liver Disease

###### Impaired Liver Function

Do not use TriLo-Marzia in women with liver disease, such as acute viral hepatitis or severe (decompensated) cirrhosis of liver [see **CONTRAINDICATIONS** (4)]. Acute or chronic disturbance of liver function may necessitate the discontinuation of COC use and return of liver function to normal and COC cessation has been evaluated discontinues TriLo-Marzia if jaundice develops.

###### Liver Tumors

TriLo-Marzia is contraindicated in women with benign and malignant liver tumors [see **CONTRAINDICATIONS** (4)]. Hepatic adenomas are associated with COC use. An estimate of the attributable risk is 3 to 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 risk of liver cancers in COC users is less than one case per million users.

##### 5.3 Risk of Liver Enzyme Elevations with Concomitant Hepatitis C Treatment

During clinical trials with the Hepatitis C combination drug regimen that contains ombitasvir/paritapavir/sofosbuvir, with or without daclatasvir, 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, than in women using TriLo-Marzia prior to starting therapy with the combination drug regimen ombitasvir/paritapavir/sofosbuvir, with or without daclatasvir [see **CONTRAINDICATIONS** (4)]. TriLo-Marzia can be restarted approximately 2 weeks following completion of treatment with the Hepatitis C combination drug regimen.

##### 5.4 High Blood Pressure

TriLo-Marzia is contraindicated in women with uncontrolled hypertension or hypertension with vascular disease [see **CONTRAINDICATIONS** (4)]. For women with well-controlled hypertension, monitor blood pressure and stop TriLo-Marzia if blood pressure rises significantly.

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

##### 5.5 Gallbladder Disease

Studies suggest a small increased relative risk of developing gallbladder disease among COC users. Use of COCs may worsen existing gallbladder disease. A meta-analysis of COC-related cholelithiasis predicts an increased risk with subsequent COC use. Women with a history of pregnancy-related cholelithiasis may be at an increased risk for COC related cholelithiasis.

##### 5.6 Carbohydrate and Lipid Metabolic Effects

Carefully monitor diabetic and diabetic women who take TriLo-Marzia. COCs may decrease glucose tolerance.

Consider alternative contraception for women with uncontrolled diabetes. 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.

##### 5.7 Headache

A woman taking TriLo-Marzia develops new headaches that are recurrent, persistent, or severe, evaluate the cause and discontinue TriLo-Marzia if indicated.

Consider discontinuation of TriLo-Marzia in the case of increased frequency or severity of migraines during COC use, which may be prodromal of a cerebrovascular event.

##### 5.8 Bleeding Irregularities and Amenorrhea

###### Unscheduled Bleeding and Spotting

Unscheduled (breakthrough or intermenstrual) bleeding and spotting sometimes occur in patients on COCs, especially during the first three months of use. If bleeding persists or occurs after previously regular cycles, check for causes such as pregnancy or malabsorption of ethinyl estradiol and progestin. The following bleeding irregularities may resolve over time, with a change to a different combination product:

• the clinical trial of TriLo-Marzia, the frequency and duration of unscheduled bleeding and spotting was assessed in 1,673 women (11,015 evaluable cycles). A total of 3 malabsorption of ethinyl estradiol and progestin was observed in TriLo-Marzia, as well as 10 bleeding irregularities. Based on data from the clinical trial, 78.1% of women using TriLo-Marzia experienced unscheduled bleeding per cycle in the first year. The percent of women who experienced unscheduled bleeding tended to decrease over time.

###### Amenorrhea and Oligomenorrhea

Women who use TriLo-Marzia may experience amenorrhea. Some women may experience amenorrhea or oligomenorrhea after discontinuation of COCs, especially when such a condition was pre-existent.

If scheduled (withdrawal) bleeding does not occur, consider the possibility of pregnancy. If the patient has not adhered to the prescribed dosing schedule (missed one or more tablets or started taking them on a day that she should have), consider the possibility of pregnancy at the time of the first missed period and take appropriate diagnostic measures. If the patient has adhered to the prescribed regimen and misses two consecutive periods, rule out pregnancy.

##### 5.9 COC Use Before or During Early Pregnancy

Extensive epidemiologic 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 the first trimester, and there are no data on reduction defects are concerned, when oral contraceptives are taken inadvertently during early pregnancy. Discontinue TriLo-Marzia use if pregnancy is confirmed.

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

##### 5.10 Depression

Carefully observe women with a history of depression and discontinue TriLo-Marzia if depression recurs to a serious degree.

##### 5.11 Malignant Neoplasms

###### Breast Cancer

TriLo-Marzia is contraindicated in females who currently have or have had breast cancer because breast cancer may be hormone 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 oral (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 and recent users 1-6 months since last usage and current users with longer duration of COC use [see **POSTMARKETING EXPERIENCE** (6.2)].

###### Cervical Cancer

Some studies suggest that COC use has been associated with an increase in the risk of cervical cancer or intraepithelial neoplasia. However, there continues to be controversy about the extent to which such findings may be due to differences in sexual behavior and other factors.

##### 5.12 Effect on Binding Globulins

The estrogen component of COCs may raise the serum concentrations of thyroxine-binding globulin, sex hormone-binding globulin, and cortisol-binding globulin. The dose of replacement thyroid hormone or cortisol therapy may need to be increased.

##### 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 healthcare.

##### 5.14 Hereditary Angioedema

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

##### 5.15 Chloasma

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 TriLo-Marzia.

#### 6 ADVERSE REACTIONS

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

- Serious cardiovascular events and stroke [see **BOXED WARNING** and **WARNINGS AND PRECAUTIONS** (5.1)]
- Vascular events [see **WARNINGS AND PRECAUTIONS** (5.1)]
- Liver disease [see **WARNINGS AND PRECAUTIONS** (5.2)]

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 rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice. The safety of TriLo-Marzia was evaluated in 1,723 subjects who participated in a randomized, partially blinded, multicenter, active-controlled clinical trial of TriLo-Marzia for contraception. This trial examined health, reproductive, and safety outcomes in 18 to 45 (mean 30.7) women aged 18 to 45 years of age, who were sexually active with regular coitus. Subjects were followed for up to 13 28-day cycles.

###### Common Adverse Reactions (≥ 2% of subjects)

The most common adverse reactions reported by at least 2% of the 1,723 women using the 28-day regimen were the following in order of decreasing incidence: headache (16.1%), nausea (15.1%), dizziness (14.1%), breast discomfort (13.1%), weight increase (12.1%), menstrual discomfort (12.1%), menstrual disorder (including dysmenorrhea, menstrual discomfort, menstrual disorder) (9.2%), mood disorders (including depression, mood elevated, mood swings and depressed mood) (7.7%), acne (5.1%), vulvovaginal infection (3.5%), abdominal distention (2.8%), weight increased (2.4%), fatigue (2.3%).

###### Adverse Reactions Leading to Study Discontinuation

In the clinical trial of TriLo-Marzia 4% of subjects discontinued the trial due to an adverse reaction. The most common adverse reactions leading to discontinuation were



## 12.2 Pharmacodynamics

No specific pharmacodynamic studies were conducted with TriLo-Maria.

## 12.3 Pharmacokinetics

### Absorption

Norgestimate (NGM) and EE are rapidly absorbed following oral administration. NGM is rapidly and completely metabolized by first pass (intestinal and/or hepatic) mechanisms to norgestrelone (NGNO) and norgestrel (NG), which are the major active metabolites of NGM.

Main pharmacokinetic parameters for NGM, NG and EE during three cycles of administration of TriLo-Maria are summarized in Table 3.

Peak serum concentrations of NGM and EE were generally reached by 2 hours after administration of TriLo-Maria. Accumulation (observed multiple dosing) of the 0.18 mg and 0.025 mg EE were approximately 1.5 and 1.8 times (both approximately 1.5 fold) for EE compared with single dose administration, in agreement with that predicted based on linear kinetics of NGM and EE. The pharmacokinetics of NGM are dose proportional following NGM doses of 0.18 to 0.25 mg. Steady state conditions for NGM following each NGM dose and for EE were achieved during the three cycle study. Non-linear accumulation (1.5 to 1.4 fold) of NG was observed as a result of high affinity binding to SHBG, which limits its biological activity.

**Table 3 Summary of NGM, NG and EE pharmacokinetic parameters.**

Study	Cycle	Day	Conc.	Time (h)	AUC <sub>0-24</sub> (ng·h/mL)	C <sub>max</sub> (ng/mL)	t <sub>1/2</sub> (h)
NGM (n=17)	1	1	0.92 (0.77)	1.8 (1.0)	5.86 (1.54)	NC	NC
		7	1.82 (0.63)	1.8 (0.1)	11.3 (3.7)	NC	NC
		14	1.82 (0.59)	1.8 (0.7)	11.9 (3.7)	NC	NC
		21	1.82 (1.44)	1.8 (0.7)	11.6 (3.6)	28.4 (16.6)	NC
NGM/NG (n=17)	1	1	0.82 (0.34)	2.0 (1.1)	2.44 (1.04)	NC	NC
		7	1.24 (0.30)	1.9 (0.9)	2.9 (1.1)	NC	NC
		14	2.11 (1.33)	4.0 (0.3)	46.7 (24.8)	NC	NC
		21	2.11 (1.33)	4.0 (0.3)	46.7 (24.8)	18.4 (9.3)	NC
EE (n=17)	1	1	35.8 (10.1)	1.7 (0.5)	421 (138)	NC	NC
		7	32.1 (25.7)	1.8 (0.3)	282 (200)	NC	NC
		14	36.9 (28.3)	1.8 (0.3)	296 (233)	NC	NC
		21	35.9 (28.3)	1.8 (0.3)	271 (200)	17.4 (8.4)	NC

NC = not calculated

NGM = norgestestimate, NG = norgestrel, EE = ethinyl estradiol  
NGNO = norgestrelone, NG = norgestrel, EE = ethinyl estradiol  
AUC<sub>0-24</sub> = area under serum concentration vs. time curve from 0 to 24 hours, t<sub>1/2</sub> = elimination half-life, units for all analyses: n = 17  
Units for EE: nM, C<sub>max</sub> = ng/mL, AUC<sub>0-24</sub> = ng·h/mL

### Food Effect:

The effect of food on the pharmacokinetics of TriLo-Maria has not been studied.

### Distribution

NGM and NG are highly bound (>97%) to serum proteins. NGM is bound to albumin and not to SHBG, while NG is bound primarily to SHBG. EE is extensively bound (>97%) to serum albumin and its binding is not affected by the serum concentration of SHBG.

### Metabolism

NGM is extensively metabolized by first-pass mechanisms in the gastrointestinal tract and liver. NGM's primary active metabolite is NGNO. Subsequent hepatic metabolism of NGNO occurs and metabolites include NG, which is also active and serves as a hydroxylated and conjugated metabolite. Although NGM and its metabolites inhibit a variety of P450 enzymes in human liver microsomes, under the recommended dosing regimen, the in vivo concentrations of NGM and its metabolites, even at the peak serum levels, are relatively low compared to the inhibitory constants (K<sub>i</sub>). EE is also metabolized to various hydroxylated products and their glucuronide and sulfate conjugates.

### Excretion

Following 3 cycles of administration of TriLo-Maria, the mean (± SD) elimination half-life values, at steady-state, for NGM, NG and EE were 28.1 (± 10.6) hours, 30.4 (± 10.2) hours and 17.7 (± 4.6) hours, respectively (Table 2). The metabolites of NGM and EE are eliminated by renal and fecal pathways.

### Use in Specific Populations

#### Effects of Body Weight, Body Surface Area, and Age:

The effects of body weight, body surface area, age and race on the pharmacokinetics of NGM, NG and EE were evaluated in 19 healthy women using pooled data following single dose administration of NGM 0.18 or 0.25 mg/EE 0.025 mg tablets in four pharmacokinetic studies. Increasing body weight and body surface area were each associated with decreases in C<sub>max</sub> and AUC<sub>0-24</sub> values for NGM and EE and increases in C<sub>max</sub> and AUC<sub>0-24</sub> values for EE. Increasing body weight by 10 kg is predicted to reduce the following parameters: NGM C<sub>max</sub> by 9% and AUC<sub>0-24</sub> by 17%, NG C<sub>max</sub> by 17% and AUC<sub>0-24</sub> by 40%, EE C<sub>max</sub> by 15% and AUC<sub>0-24</sub> by 12%. These changes were statistically significant. Increasing age was associated with an increase in C<sub>max</sub> and AUC<sub>0-24</sub> values for NGM and EE. These changes were statistically significant, but trends were not significant for EE. Only a trend to moderate increase (5 to 40% of the overall variability in the pharmacokinetics of NGM and EE following TriLo-Maria tablets) may be explained by any or all of the above demographic parameters.

## 13 NONCLINICAL TOXICOLOGY

### 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

(see WARNINGS AND PRECAUTIONS (5.2, 5.11) and USE IN SPECIFIC POPULATIONS (6.8))

## 14 CLINICAL STUDIES

In an active controlled clinical trial lasting 12 months, 1,673 women, 18 to 45 years old completed 11,003 cycles of TriLo-Maria use and a total of 20 pregnancies were reported as TriLo-Maria users. The racial demographic of those treated with TriLo-Maria was: Caucasian (86%), African-American (6%), Asian (2%), and Other (6%). There were no exclusions on the basis of weight, the weight change for women treated was 10 to 340 lbs, with a mean weight of about 142 lbs. The pregnancy rate in women aged 18 to 35 years was approximately 2.6 pregnancies per 100 women of use.

## 16 HOW SUPPLIED/STORAGE AND HANDLING

### 16.1 How Supplied

TriLo-Maria are available in a blister (NDC 68180-837-71) containing 28 tablets packed in a pouch (NDC 68180-837-71). Such three pouches are packaged in a carton (NDC 68180-837-73).

Each blister (28 tablets) contains in the following order:  
• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E21' on the other side contains 0.18 mg norgestimate and 0.025 mg ethinyl estradiol

• 1 light blue, round, film-coated tablet, debossed with 'L1' on one side and 'E22' on the other side contains 0.25 mg norgestimate and 0.025 mg ethinyl estradiol

• 7 blue, round, film-coated tablets, debossed with 'L1' on one side and 'E23' on the other side contains 0.25 mg norgestimate and 0.025 mg ethinyl estradiol

• 7 green, round, biconvex, film-coated tablets (non-hormonal placebo) debossed with 'L1' on one side and 'E24' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E25' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E26' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E27' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E28' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E29' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E30' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E31' on the other side contains inert ingredients

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• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E36' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E37' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E38' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E39' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E40' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E41' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E42' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E43' on the other side contains inert ingredients

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• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E46' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E47' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E48' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E49' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E50' on the other side contains inert ingredients

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• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E73' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E74' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E75' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E76' on the other side contains inert ingredients

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• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E83' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E84' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E85' on the other side contains inert ingredients

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• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E88' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E89' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E90' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E91' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E92' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E93' on the other side contains inert ingredients

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• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E95' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E96' on the other side contains inert ingredients

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• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E98' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E99' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E100' on the other side contains inert ingredients

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• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E104' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E105' on the other side contains inert ingredients

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• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E107' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E108' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E109' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E110' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E111' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E112' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E113' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E114' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E115' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E116' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E117' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E118' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E119' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E120' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E121' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E122' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E123' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E124' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E125' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E126' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E127' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E128' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E129' on the other side contains inert ingredients

• 1 white to off white, round, film-coated tablet, debossed with 'L1' on one side and 'E130' on the other side contains inert ingredients

- have any unexplained vaginal bleeding
- are pregnant
- had breast cancer or any cancer that is sensitive to female hormones

**If any of these conditions happen while you are taking Trilo-Maria, stop taking Trilo-Maria right away and talk to your healthcare provider. Use non-hormonal contraception when you stop taking Trilo-Maria.**

**What should I tell my healthcare provider before taking Trilo-Maria?**

**Tell your healthcare provider if you:**

- are pregnant or think you may be pregnant
- are diagnosed or have been diagnosed in the past
  - had yellowing of your skin or eyes (jaundice) caused by pregnancy (cholestatic of pregnancy)
- are breastfeeding or plan to breastfeed. Trilo-Maria may decrease the amount of breast milk you make. A small amount of the hormone in Trilo-Maria may pass into your breast milk. Talk to your healthcare provider about the best birth control method for you while breastfeeding.

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Trilo-Maria may affect the way other medicines work, and other medicines may affect how well Trilo-Maria works.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

**How should I take Trilo-Maria?**

**Read the instructions for use** at the end of this Patient Information.

**What are the possible serious side effects of Trilo-Maria?**

- **Like pregnancy.** Trilo-Maria may cause serious side effects, including blood clots in your lungs, heart attack, or a stroke that may lead to death. Some other examples of serious blood clots include blood clots in the legs or eyes.

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

- are taking birth control pills
- restart the same or different birth control pills after not using them for a month or more

**Call your healthcare provider or go to a hospital emergency room right away if you have:**

- leg pain that will not go away
- sudden severe shortness of breath
- sudden change in vision or blindness
- chest pain
- sudden, severe headache unlike your usual headaches
- weakness or numbness in your arm or leg
- trouble speaking

**Other serious side effects include:**

- **liver problems, including:**
  - rare liver failure
  - jaundice (cholestatic), especially if you previously had cholestasis of pregnancy. Call your healthcare provider if you have yellowing of your skin or eyes

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

• **gallbladder problems**

• **changes in the sugar and fat (cholesterol and triglycerides) levels in your blood**

• **worsening headaches including migraine headaches**

• **irregular or unusual vaginal bleeding and spotting between your menstrual periods, especially during the first 3 months of taking Trilo-Maria**

• **possible cancer in your breast and cervix**

• **swelling of your skin especially around your mouth, eyes, and in your throat (angioedema).** Call your healthcare provider if you have a swollen face, lips, mouth, tongue or throat, which may lead to difficulty breathing or breathing. Your chance of having angioedema is higher if you have a history of angioedema.

• **dark patches of skin around your forehead, nose, cheeks and around your mouth, especially during pregnancy (Rosacea).** Women who tend to get rosacea should avoid spending a long time in sunlight. Wearing hats and under sun lamps while taking Trilo-Maria. Use sunscreen if you have to be in the sunlight.

**What are the most common side effects of Trilo-Maria?**

- headache (including migraine)
- nausea and vomiting
- breast problems
  - tenderness, pain and discomfort
  - enlargement and swelling
  - discharge
  - nipple pain
- cramp pain
- pain with your periods (menstrual cycle)
- mood changes, including depression
- acne
- vaginal infections
- bloating
- weight gain
- fatigue

These are not all the possible side effects of Trilo-Maria. For more information, ask your healthcare provider or pharmacist.

You may report side effects to the FDA at 1-800-FDA-1088.

You may also report side effects to Lupin Pharmaceuticals, Inc. at 1-800-399-2562 or you can visit the Lupin website at [www.lupinpharmaceuticals.com](http://www.lupinpharmaceuticals.com).

**What else should I know about taking Trilo-Maria?**

- If you are a candidate for any lab tests, tell your healthcare provider you are taking Trilo-Maria so your lab tests may be affected by Trilo-Maria.
- Trilo-Maria does not protect against HIV infection (AIDS) and other sexually transmitted infections.

**How should I store Trilo-Maria?**

- Store Trilo-Maria at room temperature between 68° to 77°F (20° to 25°C).
- Keep Trilo-Maria and all medicines out of the reach of children.
- Store away from light.

**General information about the safe and effective use of Trilo-Maria.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Trilo-Maria for a condition for which it was not prescribed. Do not give Trilo-Maria to other people, even if they have the same symptoms that you have.

The Patient Information summarizes the most important information about Trilo-Maria. You can ask your pharmacist or healthcare provider for information about Trilo-Maria that's written for health professionals.

For more information, call Lupin Pharmaceuticals, Inc. at 1-800-399-2562 or you can visit the Lupin website at [www.lupinpharmaceuticals.com](http://www.lupinpharmaceuticals.com).

**Does hormonal birth control 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 if I want to become pregnant?**

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

**What should I know about my period when taking Trilo-Maria?**

Your periods may be lighter and shorter than usual. Some women may miss a period. Irregular vaginal bleeding or spotting may happen while you are taking Trilo-Maria.

especially during the first few months of use. This usually is not a serious problem. It is important to continue taking your pills on a regular schedule to prevent a pregnancy.

**What are the ingredients in Trilo-Maria?**

**Active ingredients:** Each white to off-white, light tan, and blue pill contains norgestimate and ethinyl estradiol.

**Inactive ingredients:**

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

Light blue pills: anhydrous lactose, croscarmellose sodium, FDSC Blue No. 2, Aluminum Lake, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone and titanium dioxide.

Blue pill: anhydrous lactose, croscarmellose sodium, FDSC Blue No. 2, Aluminum Lake, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone and titanium dioxide.

Green pill: croscarmellose sodium, FDSC Blue No. 2, Aluminum Lake, hypromellose, iron oxide yellow, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol and titanium dioxide.

## INSTRUCTIONS FOR USE

**Trilo-Maria (TRY-LOW-mar-ZEE-uh)**

**(norgestimate and ethinyl estradiol tablets USP)**

**Important information about taking Trilo-Maria**

- Take 1 pill every day at the same time. Take the pill in the order directed on your blister.

Do not skip your pills, even if you do not have sex often. If you miss pills (including starting the pack late) you could get pregnant. The more pills you miss, the more likely you are to get pregnant.

If you have trouble remembering to take Trilo-Maria, talk to your healthcare provider. When you first start taking Trilo-Maria, spotting or light bleeding in between your periods may occur. Contact your healthcare provider if this does not go away after a few months.

Go back to your stomach (nauseous), especially during the first few months of taking Trilo-Maria. If you feel sick to your stomach, do not stop taking the pill. The problem will usually go away. If your nausea does not go away, call your healthcare provider.

Missing pills can also cause spotting or light bleeding, even when you take the missed pills late. On the days you take 2 pills to make up for missed pills, use **What should I do if I miss any Trilo-Maria pill?** below. You could also use a latex sock to your stomach.

It is not uncommon to miss a period. However, if you miss a period and have not taken Trilo-Maria according to directions, or miss 2 periods in a row, or feel like you may be pregnant, call your healthcare provider. If you have a positive pregnancy test, you should stop taking Trilo-Maria.

If you have vomiting or diarrhea within 3 to 4 hours of taking your pill, take another pill the same day from your extra blister. If you do not have an extra blister, take the next pill in your blister. Continue on days as your remaining pills in order. Start the first pill of your next blister the day after finishing your current blister. The pill is 1 day earlier in your blister. Continue on your next blister.

If you have vomiting or diarrhea for more than 1 day, your birth control pills may not work as well. Use an additional birth control method, like condoms and a spermicide, until you check with your healthcare provider.

Stop taking Trilo-Maria at least 4 weeks before you have major surgery and do not restart after the surgery without asking your healthcare provider. Be sure to use other forms of contraception (like condoms and spermicide) during this time period.

**Before you start taking Trilo-Maria:**

- Decide what time of day you want to take your pill. It is important to take it at the same time every day, in the order as directed on your blister.
- Have backup contraception (condoms and spermicide) available and if possible, an extra full pack of pills as needed.

**When should I start taking Trilo-Maria?**

**If you start taking Trilo-Maria and you have not used a hormonal birth control method before:**

- **Start on Day 2:** Start taking your birth control pill. You can either start on a Sunday (Sunday Start) or on the first day (Day 1) of your natural menstrual period (Day 1 Start). Your healthcare provider should tell you when to start taking your birth control pill.

**If you use the Sunday Start:** use non-hormonal back-up contraception such as condoms and spermicide for the first 7 days that you take Trilo-Maria. You do not need backup contraception if you use the Day 1 Start.

**If you start taking Trilo-Maria and you are switching from another birth control pill:**

- Start your new Trilo-Maria pack on the same day that you would start the next pack of your previous birth control method.
- Do not continue taking the pill from your previous birth control pack.

**If you start taking Trilo-Maria and previously used a vaginal ring or transdermal patch:**

- Start taking Trilo-Maria on the day you would have replaced the next ring or patch.

**If you start taking Trilo-Maria and you are switching from a progestin-only method such as an implant or injection:**

- Start taking Trilo-Maria on the day of removal of your implant or on the day when you would have had your next injection.

**If you start taking Trilo-Maria and you are switching from an intrauterine device or system (IUD or IUS):**

- Start taking Trilo-Maria on the day of removal of your IUD or IUS.
- You do not need back-up contraception if your IUD or IUS is removed on the first day (Day 1) of your period. If your IUD or IUS is removed on any other day, use non-hormonal back-up contraception such as condoms and spermicide for the first 7 days that you take Trilo-Maria.

**Keep a calendar to track your period.**

**If this is the first time you are taking birth control pills, read, "When should I start taking Trilo-Maria?"** above. Follow these instructions for either a **Sunday Start** or **Day 1 Start**.

**Sunday Start**

You will use a **Sunday Start** if your healthcare provider told you to take your first pill on a Sunday.

- Take pill 1 on the Sunday **after your period starts**.
- If your period starts on a Sunday, take pill 1 that day and refer to Day 1 Start instructions below.

Take 1 pill every day in the order on the blister at the same time each day for **28** days.

After taking the last pill on **Day 28** from the blister, start taking the first pill from a new pack on the same day of the week as the first pill (Sunday). Take the first pill in the new pack whether or not you are having your period.

Use non-hormonal back-up contraception such as condoms and spermicide for the first 7 days of the first cycle that you take Trilo-Maria.

**Day 1 Start**

You will use a **Day 1 Start** if your doctor told you to take your first pill (Day 1) on the

**First day of your period.**

- Take 1 pill every day in the order of the blister, at the same time each day, for 28 days.
- After taking the last pill on Day 28 from the blister, start taking the first pill from a new pack, on the same day of the week as the first pill. Take the first pill in the new pack whether or not you are having your period.

**Instructions for using your blister:**

**Each new blister has 28 pills:**

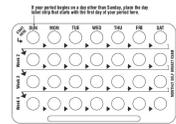
- 7 white to off-white pills with horizontal lines, for Days 1 to 7
- 7 light blue pills with horizontal lines, for Days 8 to 14
- 7 blue pills with horizontal lines, for Days 15 to 21
- 7 green pills (without horizontal lines), for Days 22 to 28.

**Step 1. SET THE DAY on your Blister**

**Sunday Start:** Each blister has been preprinted with the days of the week, starting with Sunday, to facilitate a Sunday-Start regimen.

**Day 1 Start:**

- Use different day label strips of the week, have been provided with this pack in order to accommodate a Day 1 Start regimen.
- Place the day label strip that starts with the first day of your period. Place this day label strip over the area that has the days of the week (starting with Sunday) pre-printed on the blister (blister figure below).



**Step 2. Remove pill "1" by pushing down on the pill.** The pill will come out through a hole in the back of the blister.

**Step 3. Swallow the pill.** You will take 1 pill every day, at the same time each day.

**Step 4. Wait 24 hours to take your next pill.** Continue to take 1 pill each day until all the pills have been taken.

**Step 5. Take your pill at the same time every day.** It is important to take the correct pill each day and not miss any pills. To help you remember, take your pill at the same time as another daily activity, like turning off your alarm clock or brushing your teeth.

**Step 6. When your blister is empty.** You will start a new blister on the day after pill 28. Remember to take your first pill in every vial on the same day of the week, no matter when your next period starts.

**What should I do if I miss any Tri-Le-Marzia pills?**

**If you miss 1 pill in Weeks 1, 2, or 3, follow these steps:**

- 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.
- Then continue taking 1 pill every day until you finish the pack.
- You do not need to use a back-up birth control method if you have sex.

**If you miss 2 pills in Week 1 or Week 2 of your pack, follow these steps:**

- Take the 2 missed pills as soon as possible and the next 2 pills the next day.
- Then continue to take 1 pill every day until you finish the pack.
- 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 missing your pills.

**If you miss 2 pills in a row in Week 3, or you miss 3 or more pills in a row during Weeks 1, 2, or 3 of the pack, follow these steps:**

- If you are a Day 1 Starter:
  - Throw out the rest of the pill pack and start a new pack that same day.
  - Throw out the rest of the pill pack and start a new pack that same day.
- If you are a Day 2 Starter:
  - Throw out the rest of the pill pack and start a new pack that same day.
  - 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 may not become pregnant if you have sex during the first 7 days after you restart your pills. 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.

**If you are a Sunday Starter:**

- Keep taking 1 pill every day until Sunday. On Sunday, throw out the rest of the pack and start a new pack of pills that same day.
- 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.

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

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India

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Revised: November 2024 ID#: 277632

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL**

TRI-LO-MARZIA™ (norgestimate and ethinyl estradiol) tablets USP

0.18 mg 0.025 mg, 0.215 mg 0.025 mg, 7.0.25 mg 0.025 mg

28 Day Regimen

Blister Pack

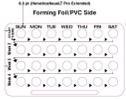
NDC 68180-837-71

28 Tablets



**Is your pregnancy risk higher than before? See how.**

Forming Fallopian Tube



TRI-LO-MARZIA™ (norgestimate and ethinyl estradiol) tablets USP

0.18 mg 0.025 mg, 0.215 mg 0.025 mg, 7.0.25 mg 0.025 mg

28 Day Regimen

Pouch

NDC 68180-837-71

28 Tablets



TRI-LO-MARZIA™ (norgestimate and ethinyl estradiol) tablets USP

0.18 mg 0.025 mg, 0.215 mg 0.025 mg, 7.0.25 mg 0.025 mg

28 Day Regimen

Carton Pack

NDC 68180-837-73

3 Blisters of 28 Tablets Each



TRI-LO-MARZIA				
norgestimate and ethinyl estradiol tablets USP				
<b>Product Information</b>				
Product Name	TRINORGESTIMATE/ETHINYL ESTRADIOL TABLETS	How Code (Source)	NDC 68180-837	
<b>Packaging</b>				
#	How Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC 68180-837	3 x 1 Unit	01/2006	

