Glenmark
A new way for a new world

MARKET WITHDRAWAL RETURN RESPONSE FORM

NORGESTIMATE AND ETHINYL ESTRADIOL TABLETS USP, 0.18 MG / 0.035 MG, 0.215 MG / 0.035 MG, 0.25 MG / 0.035 MG
3 X 28 tablet blister pack
(NDC 68462-565-29)
Retail Level
12/30/2025

Please fill out this form completely. By doing so, this will acknowledge that you have read and understand the withdrawal instructions and have taken the appropriate action.

Customer Name:	DEA#:	
DEA # is required, if it is not provided, the processing of your form will be delayed.		
Address:		
City:	State:	Zip:
Contact Name (Please Print):		
Telephone#:	Email:	
Contact Signature:	Date:	
DEBIT MEMO# (If unsure, leave blank):		

Wholesaler Information if not directly purchased from Glenmark Pharmaceuticals Inc.:

Wholesaler Name:	DEA#:	
City:	State:	Zip:

I have checked my stock and communicated to my customers at the appropriate level:

□ I confirm that all locations that received the impacted products have been notified to the Retail level _____(Initial and date)

□ I do not have any stock of the market withdrawn items. **OR**

□ I have quarantined and listed in the box below the quantity of market withdrawn units and I will be returning to Inmar, as soon as possible. Upon receipt of this Response Form, Inmar, will issue return authorization label(s) Please indicate the # of needed box labels_____

Norgestimate and Ethinyl Estradiol Tablets USP, 0.18 mg/ 0.035 mg, 0.215 mg/ 0.035 mg, 0.25 mg / 0.035 mg

Sr. No.	NDC Code	Batch Number	Pack size	Expiry Date	Total Full/ Sealed and Partial/ Open Blister Count
1	68462-565-29	20240383	3 X 28 tablet blister pack	December 2025	
2	68462-565-29	20240532	3 X 28 tablet blister pack	January 2026	
3	68462-565-29	20240566	3 X 28 tablet blister pack	January 2026	
4	68462-565-29	20240572	3 X 28 tablet blister pack	March 2026	
5	68462-565-29	20250080	3 X 28 tablet blister pack	June 2026	
6	68462-565-29	20250205	3 X 28 tablet blister pack	August 2026	
7	68462-565-29	20250321	3 X 28 tablet blister pack	October 2026	

If you have any questions regarding this form or product return please contact Inmar at **877-545-4694.** Office hours 9am to 5pm EST Mon thru Fri.

Please fax this form to: 1-817-868-5362 or E-mail rxrecalls@inmar.com

Market Withdrawal Event ID N131420 | RCL323-25

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DRUG MARKET WITHDRAWAL

NORGESTIMATE AND ETHINYL ESTRADIOL TABLETS USP, 0.18 MG / 0.035 MG, 0.215 MG / 0.035 MG, 0.25 MG / 0.035 MG
3 X 28 Tablet blister pack
(NDC 68462-565-29)

December 30, 2025

Dear Pharmacy, Wholesale and Retail Customer:

This is to inform you that Glenmark is initiating a Market Withdrawal at the Retail level involving the following prescription product:

Norgestimate and Ethinyl Estradiol Tablets USP, 0.18 mg/ 0.035 mg, 0.215 mg/ 0.035 mg, 0.25 mg/ 0.035 mg

Sr. No.	NDC Code	Batch Number	Pack size	Expiry Date
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6	68462-565-29	20250205	3 X 28 tablet blister pack	August 2026
7	68462-565-29	20250321	3 X 28 tablet blister pack	October 2026

Glenmark is initiating a market withdrawal at the ***Retail level*** for the above-identified batches of Norgestimate and Ethinyl Estradiol Tablets USP, 0.18 mg/ 0.035 mg, 0.215 mg/ 0.035 mg, and 0.25 mg/ 0.035 mg.

An out of trend (OOT) result was reported in Norgestimate and Ethinyl Estradiol Tablets USP 0.18 mg/ 0.035mg for the Chromatographic Purity (Method-I by HPLC) test for the batch # 20240532 (Expiry – January 2026) at long term (25°C/60% RH) 12 month time interval, wherein 17-acetyl-Levonorgestrel impurity was observed to be 2.58% against the specification limit of NMT 3.0%. The result for 17-acetyl-Levonorgestrel impurity and all the other test parameters comply with the registered specification. The internal OOT limit for 17-acetyl-Levonorgestrel impurity is not more than 2.4% (NMT 80% of Specification). The batch was charged in long-term stability as an annual batch for the year 2024.

Statistical predictive analysis was performed for 17-acetyl-Levonorgestrel impurity for the above OOT batch # 20240532 and it is observed that the 17-acetyl-Levonorgestrel impurity result for 0.18 mg/ 0.035 mg strength at the terminal time point (Expiry) of 18 months is likely to be towards

Glenmark Pharmaceuticals Inc. USA 619 River Drive, Elmwood Park, NJ 07407
T: 1 201 684 8000 F: 1 201 831 0080 www.glenmarkpharma.com/usa

the higher side of the specification or Out of Specification (OOS) in comparison to other two (2) strengths 0.215 mg/ 0.035 mg and 0.25 mg/ 0.035 mg which are expected to comply to the specification.

Since the increase in 17-acetyl-Levonorgestrel impurity is observed during stability study and it may be OOS at the expiry time point, though meeting specification currently, as an abundance of caution, Glenmark is initiating a market withdrawal of all the seven (7) within-shelf-life batches of Norgestimate and Ethinyl Estradiol Tablets USP, 0.18 mg/ 0.035 mg, 0.215 mg/ 0.035 mg, and 0.25 mg/ 0.035 mg manufactured before implementation of CAPA.

As of today, a total of 7 batches are within shelf life, which were manufactured before the implementation of CAPA. These 7 batches are within the age of 8 to 18 months, and no OOS failures were reported for these batches proposed under this market withdrawal.

The overall investigation concluded the OOT result as valid, and the root cause for the OOT result is as follows:
The packaging configuration of the drug product includes blister card containing 28 tablets along with 3g Silica Desiccant and paper components such as leaflet, start label, and carry case in the pouch. The paper component has inherent moisture. The drug product is sensitive to oxidative degradation, and the paper components available in the pouch contribute to moisture, thereby inducing the oxidative degradation.

Hence, as part of CAPA, Glenmark filed CBE-0 on September 8, 2025, to propose change in packaging configuration from "Blister of 28 tablets sealed in a cold-seal card. One cold-seal card with blister along with one 3g Sorb-It pouch, one carry case with start-day label, and one patient information leaflet packed in a printed pouch and sealed. Three such pouches packed in a carton along with a leaflet" to "Blister of 28 tablets, along with one 5g two-in-one desiccant pouch, packed in a printed pouch and sealed. Three such pouches packed in a carton along with one package insert containing three sets of carry cases, start-day sticker labels, and patient information." With the revised packaging configuration, the paper components are placed outside the sealed pouch. Further commercial batches will be manufactured with the implementation of the above CAPA.

Please see the details of product batches listed in the above table and refer to the enclosed product labels for ease in identifying the product.

Please examine your inventory, and if you have any inventory available for the batches specified in the above table, you should quarantine such product immediately and not dispense any further product from these lots. Glenmark Pharmaceuticals Inc., USA, initiated shipment of this product on September 5, 2024.

In addition, if you are a wholesaler/ distributor who has further distributed this product, please identify those retail customers and notify them at once of this market withdrawal. Your notification to your retail customers may be enhanced by including a copy of this market withdrawal

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notification letter. Again, this market withdrawal should be carried out to the retail level only. Because this is not a consumer-level market withdrawal, notice to the consumer level is not required.

Glenmark is requesting the batches specified in the above table to be returned to Inmar Rx Solutions (address below) using the Postage Paid Product Return label that was provided in your Market Withdrawal Return Packet.

Inmar Rx Solutions
3845 Grand Lakes Way
Grand Prairie, TX 75050

Please complete and return the enclosed response form preferably within 72 hours of receipt of this notification. Please either fax your response to 817-868-5362 or email to Rxrecalls@Inmar.com.

If you have any questions regarding your market withdrawal return please contact Inmar at **877-545-4694.** Inmar office hours are Monday through Friday, from 9 am to 5 pm EST.

The FAR was submitted to the Agency on December 22, 2025, to notify about this market withdrawal.

Thank you for your cooperation,

Sincerely,

thomas.callaghan@glenmarkpharma.com
Digitally signed by thomas.callaghan@glenmarkpharma.com
Date: 2025.12.30 11:54:32 -05'00'

GLENMARK PHARMACEUTICALS INC., USA

Thomas Callaghan

Executive Director - Regulatory Affairs, North America

US Agent for Glenmark Pharmaceuticals Limited

Enclosure(s):

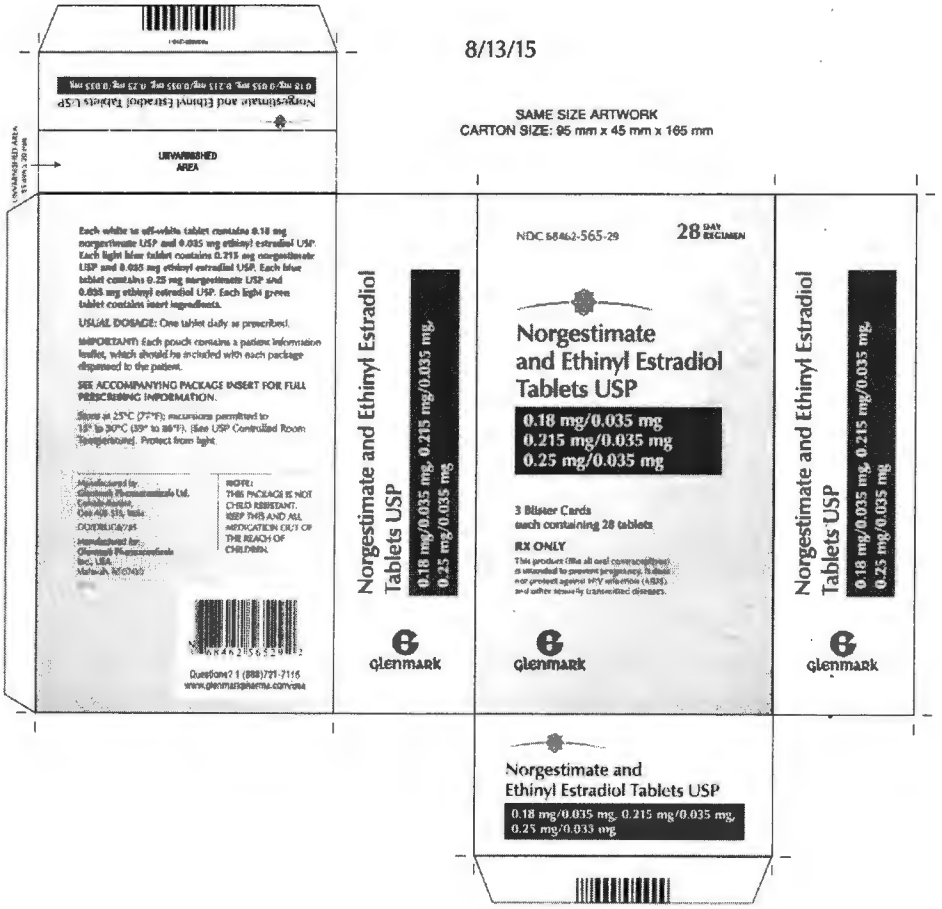
Product Labels

Market Withdrawal Return Response For

Glenmark Pharmaceuticals Inc. USA 619 River Drive, Elmwood Park, NJ 07407
T: 1 201 684 8000 F: 1 201 831 0080 www.glenmarkpharma.com/usa

Product label:

Norgestimate and Ethinyl Estradiol Tablets USP, 0.18 mg/ 0.035 mg, 0.215 mg/ 0.035 mg, 0.25 mg/ 0.035 mg.



Glenmark Pharmaceuticals Inc. USA 619 River Drive, Elmwood Park, NJ 07407
T: 1 201 684 8000 F: 1 201 831 0080 www.glenmarkpharma.com/usa

8/13/15

SAME SIZE ARTWORK
CARTON SIZE: 95 mm x 45 mm x 165 mm

UNVARNISHED AREA
95 mm x 20 mm

UNVARNISHED
AREA

Each white to off-white tablet contains 0.18 mg norgestimate USP and 0.035 mg ethinyl estradiol USP. Each light blue tablet contains 0.215 mg norgestimate USP and 0.035 mg ethinyl estradiol USP. Each blue tablet contains 0.25 mg norgestimate USP and 0.035 mg ethinyl estradiol USP. Each light green tablet contains inert ingredients.

USUAL DOSAGE: One tablet daily as prescribed.

IMPORTANT: Each pouch contains a patient information leaflet, which should be included with each package dispensed to the patient.

SEE ACCOMPANYING PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION.

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature]. Protect from light.

Manufactured by:
Glenmark Pharmaceuticals Ltd.
Colvale-Bardez,
Goa 403 513, India

GO/DRUGS/785

Manufactured for:
Glenmark Pharmaceuticals Inc., USA
Mahwah, NJ 07430

07/15

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

PE346531215-1

Norgestimate and Ethinyl Estradiol Tablets USP

0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg

Norgestimate and Ethinyl Estradiol Tablets USP

0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg

NDC 68462-565-29

28 DAY REGIMEN

Norgestimate and Ethinyl Estradiol Tablets USP

0.18 mg/0.035 mg
0.215 mg/0.035 mg
0.25 mg/0.035 mg

3 Blister Cards
each containing 28 tablets

RX ONLY

This product (like all oral contraceptives) is intended to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

64659
Norgestimate and Ethinyl Estradiol Tablets, USP

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use NORGESTIMATE AND ETHINYL ESTRADIOL TABLETS safely and effectively. See full prescribing information f AND ETHINYL ESTRADIOL TABLETS.

NORGESTIMATE and ETHINYL ESTRADIOL tablets, 0.25 mg/0.035 mg, for oral use
NORGESTIMATE and ETHINYL ESTRADIOL tablets, 0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg, for oral use

Initial U.S. Approval: 1989

WARNING: CIGARETTE SMOKING and SERIOUS CARDIOVASCULAR EVENTS

See full prescribing information for complete boxed warning.

- **Norgestimate and ethinyl estradiol tablets are contraindicated in women over 35 years old who smoke. (4)**
- **Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptives (COC) use. (4)**

RECENT MAJOR CHANGES

Contraindications, Pregnancy (4)

INDICATIONS AND USAGE

Norgestimate and ethinyl estradiol tablets are combinations of norgestimate, a progestin, and ethinyl estradiol, an estrogen, indicated for use by females of reproductive p pregnancy. (1.1)

Norgestimate and ethinyl estradiol tablets 0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg are indicated for the treatment of moderate acne vulgaris in females at lea who have no known contraindications to oral contraceptive therapy and have achieved menarche.

Norgestimate and ethinyl estradiol tablets 0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg should be used for the treatment of acne only if the patient desires an ora birth control. (1.2)

DOSAGE AND ADMINISTRATION

- Take one tablet daily by mouth at the same time every day. (2.1)
- Take tablets in the order directed on the blister pack. (2.1)
- Do not skip or delay tablet intake. (2.1)

DOSAGE FORMS AND STRENGTHS

Norgestimate and Ethinyl Estradiol Tablets, USP 0.25 mg/0.035 mg, consist of 28 round, flat faced beveled edged, uncoated tablets in the following order (3).

- 21 blue tablets each containing 0.25 mg norgestimate, USP and 0.035 mg ethinyl estradiol, USP
- 7 light green tablets (inert)

Norgestimate and Ethinyl Estradiol Tablets, USP 0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg, consist of 28 round, flat faced beveled edged, uncoated tablets in the

- 7 white to off-white tablets each containing 0.18 mg norgestimate, USP and 0.035 mg ethinyl estradiol, USP
- 7 light blue tablets each containing 0.215 mg norgestimate, USP and 0.035 mg ethinyl estradiol, USP

FULL PRESCRIBING INFORMATION: CONTENTS*

Substances increasing the plasma concentrations of COCs

Co-administration of atorvastatin or rosuvastatin and certain COCs containing ethinyl estradiol (EE) increase AUC values for EE by approximately 20 to 25%. Ascorbic acid and acetaminophen may increase plasma EE concentrations, possibly by inhibition of conjugation. CYP3A4 inhibitors such as itraconazole, voriconazole, fluconazole, grapefruit juice, or ketoconazole may increase plasma hormone concentrations.

Human immunodeficiency virus (HIV)/Hepatitis C virus (HCV) protease inhibitors, non-nucleoside reverse transcriptase inhibitors, and HIV/AIDS medications containing strong inhibitors or inducers of CYP3A

Significant changes (increase or decrease) in the plasma concentrations of estrogen and/or progestin have been noted in some cases of co-administration with HIV protease inhibitors (decrease [e.g., nelfinavir, ritonavir, darunavir/ritonavir, (fos)amprenavir/ritonavir, lopinavir/ritonavir, and tipranavir/ritonavir] or increase [e.g., indinavir and atazanavir/ritonavir]) /HCV protease inhibitors (decrease [e.g., boceprevir and telaprevir]) or with non-nucleoside reverse transcriptase inhibitors (decrease [e.g., nevirapine] or increase [e.g., etravirine]) or with HIV/AIDS medications containing strong inhibitors (e.g., cobicistat and ritonavir) or inducers of CYP3A.

7.2 Effects of Combined Oral Contraceptives on Other Drugs

- COCs containing EE may inhibit the metabolism of other compounds (e.g., cyclosporine, prednisolone, theophylline, tizanidine, and voriconazole) and increase their plasma concentrations.
- COCs have been shown to decrease plasma concentrations of acetaminophen, clofibric acid, morphine, salicylic acid, temazepam and amotrigine. Significant decrease in plasma concentration of lamotrigine has been shown, likely due to induction of lamotrigine glucuronidation. This may reduce seizure control; therefore, dosage adjustments of lamotrigine may be necessary.

Women on thyroid hormone replacement therapy may need increased doses of thyroid hormone because the serum concentration of thyroid-binding globulin increases with use of COCs.

7.3 Interference with Laboratory Tests

The use of contraceptive steroids may influence the results of certain laboratory tests, such as coagulation factors, lipids, glucose tolerance, and binding proteins.

7.4 Concomitant Use with HCV Combination Therapy – Liver Enzyme Elevation

Do not co-administer norgestimate and ethinyl estradiol tablets with HCV drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, due to potential for ALT elevations *[see Warnings and Precautions (5.3)]*

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There is no use for contraception in pregnancy, therefore, norgestimate and ethinyl estradiol tablets should be discontinued during 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 CHCs before conception or during early pregnancy.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4 percent and 15 to 20 percent, respectively.

8.2 Lactation

Risk Summary

Contraceptive hormones and/or metabolites are present in human milk. CHCs can reduce milk production in breastfeeding females. This reduction can occur at any time but is less likely to occur once breastfeeding is well-established. When possible, advise the nursing female to use other forms of contraception until she discontinues breastfeeding. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for norgestimate and ethinyl estradiol tablets and any potential adverse effects on the breastfed child from norgestimate and ethinyl estradiol tablets or from the underlying maternal condition.

8.4 Pediatric Use

Safety and efficacy of norgestimate and ethinyl estradiol tablets have been established in women of reproductive age. Efficacy is expected to be the same for post-pubertal adolescents under the age of 18 and for users 18 years and older. Use of this product before menarche is not indicated.

There was no significant difference between norgestimate and ethinyl estradiol tablets, 0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg, and placebo in mean change in total lumbar spine (L1-L4) and total hip bone mineral density between baseline and Cycle 13 in 123 adolescent females with anorexia nervosa in a double-blind, placebo-controlled, multicenter, one-year treatment duration clinical trial for the Intent To Treat (ITT) population.

8.5 Geriatric Use

Norgestimate and ethinyl estradiol tablets have not been studied in postmenopausal women and are not indicated in this population.

8.6 Hepatic Impairment

The pharmacokinetics of norgestimate and ethinyl estradiol tablets have not been studied in subjects with hepatic impairment. However, steroid hormones may be poorly metabolized in patients with hepatic impairment. 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 *[see Contraindications (4)* and *Warnings and Precautions (5.2)]*.

8.7 Renal Impairment

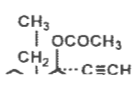
The pharmacokinetics of norgestimate and ethinyl estradiol tablets have not been studied in women with renal impairment.

10 OVERDOSAGE

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

11 DESCRIPTION

Each of the following products is a combination oral contraceptive containing the progestational compound norgestimate, USP and the estrogenic compound ethinyl estradiol, USP. Norgestimate, USP is designated as (18,19-Dinor-17-pregn-4-en-20-yn-3-one,17-(acetyloxy)-13-ethyl-,oxime,(17α)-(+)-) and ethinyl estradiol, USP is designated as (19-nor-17α-pregna,1,3,5(10)-trien-20-yne-3,17-diol).



C_{max} = peak serum concentration, t_{max} = time to reach peak serum concentration, AUC_{0-24h} = area under serum concentration vs time curve from 0 to 24 hours, $t_{1/2}$ = elimination half-life, NC = not calculated.

NGMN and NG: C_{max}= ng/mL, AUC_{0-24h}=h•ng/mL

EE: C_{max}=pg/mL, AUC_{0-24h}=h•pg/mL

Food Effect

The effect of food on the pharmacokinetics of norgestimate and ethinyl estradiol tablets has not been studied.

Distribution

NGMN and NG are highly bound (>97%) to serum proteins. NGMN is bound to albumin and not to SHBG, while NG is bound primarily to SHBG. EE is extensively bound (>97%) to serum albumin and induces an increase in the serum concentrations of SHBG.

Metabolism

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

Excretion

The metabolites of NGMN and EE are eliminated by renal and fecal pathways. Following administration of ^{14}C-norgestimate, 47% (45 to 49%) and 37% (16 to 49%) of the administered radioactivity was eliminated in the urine and feces, respectively. Unchanged NGM was not detected in the urine. In addition to 17-deacetyl norgestimate, a number of metabolites of NGM have been identified in human urine following administration of radiolabeled NGM. These include 18, 19-Dinor-17-pregn-4-en-20-yn-3-one, 17-hydroxy-13-ethyl-(17α)-(+)-18,19-Dinor-5β-17-pregnan-20-yn-3α,17β-dihydroxy-13-ethyl-(17α), various hydroxylated metabolites and conjugates of these metabolites.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

[See Warnings and Precautions (5.2, 5.10)]

14 CLINICAL STUDIES

14.1 Contraception

In three US clinical trials with norgestimate and ethinyl estradiol tablets, 0.25 mg/0.035 mg, 1,651 women aged 18 to 38 years were studied for up to 24 cycles, proving a total of 24,272 cycles of exposure. The racial demographic was about 73 to 86% Caucasian, 8 to 13% African-American, 6 to 14% Hispanic with the remainder Asian or Other (≤1%). There were no exclusions on the basis of weight; the weight range for women treated was 82 to 303 lbs, with a mean weight of about 135 lbs. The pregnancy rate was approximately 1 pregnancy per 100 women-years.

In four clinical trials with norgestimate and ethinyl estradiol tablets, 0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg, 4,756 women aged 15 to 41 years were studied for 24 cycles, providing a total of 45,244 cycles of exposure. The racial demographic was about 87 to 90% Caucasian, 6 to 10% African-American, with the remainder Asian (≤1%) or Other (2 to 5%). There were no exclusions on the basis of weight; the weight range for women treated was 80 to 310 lbs, with a mean weight of about 132 lbs. The pregnancy rate was approximately 1 pregnancy per 100 women-years.

14.2 Acne

Norgestimate and ethinyl estradiol tablets, 0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg, was evaluated for the treatment of acne vulgaris in two randomized, double-blind, placebo-controlled, multicenter, six- (28 day) cycle studies. Two hundred twenty-one patients received norgestimate and ethinyl estradiol tablets, 0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg, and 234 patients received placebo. Mean age at enrollment for both groups was 28 years. At the end of 6 months, the mean total lesion count changed from 55 to 31 (42% reduction) in patients treated with norgestimate and ethinyl estradiol tablets, 0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg, and from 54 to 38 (27% reduction) in patients similarly treated with placebo. Table 4 summarizes the changes in lesion count for each type of lesion. Based on the investigator's global assessment conducted at the final visit, patients treated with norgestimate and ethinyl estradiol tablets, 0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg, showed a statistically significant improvement in total lesions compared to those treated with placebo.

Table 4: Acne Vulgaris Indication. Combined Results: Two Multicenter, Placebo-Controlled Trials, Observed Means at Six Months (LOCF)[1] and at Baseline, Intent-to-Treat Population.

	Norgestimate and Ethinyl Estradiol Tablets, 0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg (N=221)		Placebo (N=234)		Difference in Counts between Norgestimate and Ethinyl Estradiol Tablets, 0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg and Placebo at 6 Months
# of Lesions	Counts	% Reduction	Counts	% Reduction	
INFLAMMATORY LESIONS					
Baseline Mean	19		19		
Sixth Month Mean	10	48%	13	30%	3 (95% CI: -1.2, 5.1)
NON-INFLAMMATORY LESIONS					
Baseline Mean	36		35		
Sixth Month Mean	22	34%	25	21%	3 (95% CI: -0.2, 7.8)
TOTAL LESIONS					
Baseline Mean	55		54		
Sixth Month Mean	31	42%	38	27%	7 (95% CI: 2, 11.9)

[1]LOCF: Last Observation Carried Forward

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

Norgestimate and Ethinyl Estradiol Tablets, USP 0.25 mg/0.035 mg are available in blister packs containing 28 tablets, as follows:

chart shows the chan
to get pregnant.

Fewer than 1 pregnancy per 100 women in one year

10 to 20 pregnancies per 100 women in one year

85 or more pregnancies per 10 women in one year

Who should not take
Do not take norgestin

- smoke and are ove
- had blood clots in
- had a problem with
- have certain heart clots
- had a stroke
- had a heart attack
- have high blood p
- have diabetes with
- have certain kinds vision, or any migr
- have liver problem
- take any Hepatitis dasabuvir. This m blood.
- have any unexplain
- are pregnant
- had breast cancer

If any of these conditi stop taking norgestir provider. Use non-h estradiol tablets.

What should I tell my
Tell your healthcare p

- are pregnant or thi
- are depressed no
- had yellowing of y
- are breastfeeding amount of breas estradiol may pas control method for

Tell your healthcare p

counter medicines, vit

Norgestimate and eth medicines may affect

Know the medicines y when you get a new m

How should I take nor
Read the Instructions

What are the possible

- **Like pregnancy, including blood cl examples of serio**

Serious blood clots ca
Serious blood clots ar

- first start taking b
- restart the same or