CLINICAL UPDATE

Brand Name	Zafemy™
Generic Name	norelgestromin and ethinyl estradiol transdermal system
Drug Manufacturer	Amneal Pharmaceuticals LLC

Clinical Update

TYPE OF CLINICAL UPDATE

New brand

FDA APPROVAL DATE

February 25, 2021

LAUNCH DATE

N/A

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 213950

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION(S) FOR USE

Zafemy™ is an estrogen/progestin combination hormonal contraceptive (CHC), indicated for the prevention of pregnancy in women with a BMI < 30 kg/m for whom a combined hormonal contraceptive is appropriate.

MECHANISMS OF ACTION

Zafemy™ contains 3.15 mg norelgestromin, USP (NGMN) and 0.289 mg ethinyl estradiol, USP (EE), and its delivery rate is approximately 150 mcg of NGMN, USP and 35 mcg of EE, USP per day. NGMN is the active progestin largely responsible for the progestational activity that occurs in women following application of Zafemy™ NGMN is also the primary active metabolite produced following oral administration of NGM, the progestin component of some oral contraceptive products.

Combination hormonal contraceptives act by suppression of gonadotropins. Although the primary mechanism of this action is inhibition of ovulation, other alterations include changes in the cervical mucus (which increase the difficulty of sperm entry into the uterus) and the endometrium (which reduce the likelihood of implantation).

DOSAGE FORM(S) AND STRENGTH(S)

Transdermal system: 150 mcg/day norelgestromin, USP and 35 mcg/day ethinyl estradiol, USP.

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DOSE & ADMINISTRATION

- Zafemy™ uses a 28-day (four-week) cycle. Apply a new patch to the upper outer arm, abdomen, buttock or back each week for three weeks (21 total days). Week Four is patch-free.
- Apply each new patch on the same day of the week. Wear only one patch at a time.
- Do not cut or alter the patch in any way.

EFFICACY

In 3 large clinical trials lasting 12 months, in North America, Europe and South Africa, 3,330 women (ages 18 to 45) completed 22,155 cycles of Zafemy™ patch use, the pregnancy rate in women aged 18 to 35 years was 1.07 (95% confidence interval 0.60, 1.76) per 100 woman-years of Zafemy™ patch use. The racial distribution was 91% Caucasian, 4.9% Black, 1.6% Asian, and 2.4% Other.

With respect to weight, 5 of the 15 pregnancies reported with Zafemy™ patch use were among women with a baseline body weight ≥ 198 lbs., which constituted < 3% of the study population. The greater proportion of pregnancies among women at or above 198 lbs. was statistically significant and suggests that Zafemy™ patch may be less effective in these women.

Patch Adhesion:

In the clinical trials with Zafemy™ patch, approximately 2% of the cumulative number of patches completely detached and 3% partially detached. The proportion of subjects with at least 1 patch that completely detached ranged from 2% to 6%, with a reduction from Cycle 1 (6%) to Cycle 13 (2%).