CLINICAL UPDATE

Brand Name	Taytulla®
Generic Name	gemmily
Drug Manufacturer	Chemo Research, SL

Clinical Update

TYPE OF CLINICAL UPDATE

New Generic Approval

FDA APPROVAL DATE

November 9, 2020

LAUNCH DATE

November 9, 2020

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 213317

DISPENSING RESTRICTIONS

None

Overview

INDICATION(S) FOR USE

Gemmily is indicated for use by females of reproductive age to prevent pregnancy.

MECHANISMS 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.

DOSAGE FORM(S) AND STRENGTH(S)

Gemmily consists of 28 soft gelatin capsules in the following order:

- 24 pink capsules (active), each containing 1 mg norethindrone acetate and 20 mcg ethinyl estradiol.
- 4 maroon capsules (non-hormonal placebo) each containing 75 mg ferrous fumarate which does not serve any therapeutic purpose

DOSE & ADMINISTRATION

- Take one capsule by mouth at the same time every day.
- Take capsules in the order directed on the blister pack.
- Capsules may be administered without regard to meals.

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EFFICACY

In a clinical study, 743 women 18 to 45 years of age were studied to assess the efficacy of norethindrone acetate/ethinyl estradiol tablets, for up to six 28-day cycles providing a total of 3,823 treatment-cycles of exposure. The racial demographic of all enrolled women was: 70% Caucasian, 16% African-American, 10% Hispanic, 2% Asian, and 2% Other. Women with body mass index (BMI) greater than 35 mg/m2 were excluded from the study. The weight range for those women treated was 90 to 260 pounds, with a mean weight of 147 pounds. Among the women in the study, about 40% had not used hormonal contraception immediately prior to enrolling in this study.

A total of 583 women completed 6 cycles of treatment. There were a total of 5 on-treatment pregnancies in 3,565 treatment cycles during which no backup contraception was used. The Pearl Index for norethindrone acetate/ethinyl estradiol tablets was 1.82 (95% confidence interval 0.59 - 4.25).