CLINICAL UPDATE

Brand Name	Zovia® 1/35
Generic Name	ethynodiol diacetate and ethinyl estradiol
Drug Manufacturer	Mayne Pharma Inc.

Clinical Update

TYPE OF CLINICAL UPDATE

New Brand

FDA APPROVAL DATE

N/A

LAUNCH DATE

November 13, 2020

REVIEW DESIGNATION

N/A

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 072721

DISPENSING RESTRICTIONS

Open

Overview

INDICATION(S) FOR USE

Indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception.

MECHANISMS OF ACTION

Ethinyl estradiol in combination with ethynodiol diacetate is an oral contraceptive that exerts its action by blocking ovulation through gonadotropin suppression. It also increases the difficulty of sperm entry into the uterus by altering the cervical mucus and reduces the possibility of implantation by causing a change in endometrium.

DOSAGE FORM(S) AND STRENGTH(S)

Tablet: Each tablet contains 1 mg of ethynodiol diacetate and 35 mcg of ethinyl estradiol.

DOSE & ADMINISTRATION

1 tablet orally daily at intervals of 24 hours for 21 consecutive days, then 1 white inert tablet for 7 consecutive days; repeat cycle.

EFFICACY

A phase IV trial evaluated the efficacy and safety of a monophasic oral contraceptive formulation, ethynodiol diacetate, 1 mg, plus ethinyl estradiol, 35 micrograms (EDA 1 mg with EE 35 micrograms). Nine hundred eighty-

three community-based obstetrician-gynecologists treated a total of 7,759 patients with EDA 1 mg with EE 35 micrograms for one to eight months. Clinical evaluation forms on 6,382 patients were amenable to analysis for safety (including breakthrough bleeding, ovarian cyst formation and complexion changes); 5,412 patients were evaluable for efficacy (prevention of pregnancy), with a total of 21,440 cycles recorded.

The physicians initially reported 121 (2.2%) pregnancies during the study. The researchers learned that 33 of the 84 returned 2nd questionnaires (response rate, 70%) reported that the women conceived after enrollment but before taking the oral contraceptive (OC). 36 conceived while taking it, but 8 did not take it daily. Noncompliance may have contributed to pregnancy for the remaining 28 cases. Therefore the 36 confirmed pregnancies made for a failure rate of .7%. 85.7% of the pregnancies happened in the 1st 3rd months of taking the OC. Either patient noncompliance or true medication failure accounted for treatment failure. Therefore, it is important for physicians to instruct patients on how to take OCs correctly.