

CLINICAL UPDATE

Brand Name	Nymyo®
Generic Name	norgestimate and ethinyl estradiol
Drug Manufacturer	Mayne Pharma Inc.

Clinical Update

TYPE OF CLINICAL UPDATE

New Brand

FDA APPROVAL DATE

December 2020 (date not available)

LAUNCH DATE

December 11, 2020

REVIEW DESIGNATION

N/A

TYPE OF REVIEW

N/A

DISPENSING RESTRICTIONS

Open

Overview

INDICATION(S) FOR USE

Nymyo® is an estrogen/progestin COC, indicated for use by women 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)

Nymyo® consists of 28 round, biconvex, coated tablets in the following order:

- 21 blue tablets each containing 0.250 mg norgestimate and 0.035 mg ethinyl estradiol
- 7 white tablets (inert)

DOSE & ADMINISTRATION

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

EFFICACY

This document is designed to be an informational resource to facilitate discussion and should be used neither as a basis for clinical decision-making or treatment nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.

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In three US clinical trials with norgestimate and ethinyl estradiol 0.25mg/0.035mg, 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 73-86% Caucasian, 8-13% African-American, 6-14% Hispanic with the remainder Asian or Other ($\leq 1\%$). There were no exclusions on the basis of weight; the weight range for women treated was 82-303 lbs, with a mean weight of about 135 lbs. The pregnancy rate was approximately 1 pregnancy per 100 women-years.

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