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Cyclafem 1/35 Dosage

Generic name: NORETHINDRONE 1mg, ETHINYL ESTRADIOL 0.035mg;

Dosage form: tablets

Drug class: Contraceptives

Medically reviewed by Drugs.com. Last updated on May 27, 2024.

To achieve maximum contraceptive effectiveness, Cyclafem[™] 1/35 tablets must be taken exactly as directed and at intervals not exceeding 24 hours. Cyclafem[™] 1/35 tablets are available in a blister pack tablet dispenser which is preset for a Sunday Start. Stickers designating a Day 1 Start are also provided.

Sunday Start

When taking Cyclafem[™] 1/35 tablets, the first "active" tablet should be taken on the first Sunday after menstruation begins. If the period begins on Sunday, the first "active" tablet should be taken that day. Take one active tablet daily for 21 days followed by one light-green "reminder" tablet daily for 7 days. After 28 tablets have been taken, a new course is started the next day (Sunday). For the first cycle of a Sunday Start regimen, another method of contraception such as a condom or spermicide should be used until after the first 7 consecutive days of administration.

If the patient misses one (1) "active" tablet in Weeks 1, 2, or 3, the tablet should be taken as soon as she remembers. If the patient misses two (2) "active" tablets in Week 1 or Week 2, the patient should take two (2) tablets the day she remembers and two (2) tablets the next day; and then continue taking one (1) tablet a day until she finishes the pack. The patient should be instructed to use a back-up method of birth control such as a condom or spermicide if she has sex in the seven (7) days after missing pills. If the patient misses two (2) "active" tablets in the third week or misses three (3) or more "active" tablets in a row, the patient should continue taking one tablet every day until Sunday. On Sunday the patient should throw out the rest of the pack and start a new pack that same day. The patient should be instructed to use a back-up method of birth control if she has sex in the seven (7) days after missing pills.

Complete instructions to facilitate patient counseling on proper pill usage may be found in the **DETAILED PATIENT LABELING** ("HOW TO TAKE THE PILL" section).

Day 1 Start

The dosage of Cyclafem[™] 1/35 tablets, for the initial cycle of therapy, is one "active" tablet administered daily from the 1st through the 21st day of the menstrual cycle, counting the first day of menstrual flow as "Day 1" followed by one light-green "reminder" tablet daily for 7 days. Tablets are taken without interruption for 28 days. After 28 tablets have been taken, a new course is started the next day.

If the patient misses one (1) "active" tablet in Weeks 1, 2, or 3, the tablet should be taken as soon as she remembers. If the patient misses two (2) "active" tablets in Week 1 or Week 2, the patient should take two (2) tablets the day she remembers and two (2) tablets the next day; and then continue taking one (1) tablet a day until she finishes the pack. The patient should be instructed to use a back-up method of birth control such as a condom or spermicide if she has sex in

the seven (7) days after missing pills. If the patient misses two (2) "active" tablets in the third week or misses three (3) or more "active" tablets in a row, the patient should throw out the rest of the pack and start a new pack that same day. The patient should be instructed to use a back-up method of birth control if she has sex in the seven (7) days after missing pills.

Complete instructions to facilitate patient counseling on proper pill usage may be found in the **DETAILED PATIENT LABELING** ("**HOW TO TAKE THE PILL**" section).

The use of Cyclafem[™] 1/35 tablets, for contraception may be initiated 4 weeks postpartum in women who elect not to breast feed. When the tablets are administered during the postpartum period, the increased risk of thromboembolic disease associated with the postpartum period must be considered (see **CONTRAINDICATIONS** and **WARNINGS** concerning thromboembolic disease; see also **PRECAUTIONS** for "**Nursing Mothers**"). The possibility of ovulation and conception prior to initiation of medication should be considered.

(See Discussion of Dose-Related Risk of Vascular Disease From Oral Contraceptives.)

ADDITIONAL INSTRUCTIONS

Breakthrough bleeding, spotting, and amenorrhea are frequent reasons for patients discontinuing oral contraceptives. In breakthrough bleeding, as in all cases of irregular bleeding from the vagina, nonfunctional causes should be borne in mind. In undiagnosed persistent or recurrent abnormal bleeding from the vagina, adequate diagnostic measures are indicated to rule out pregnancy or malignancy. If pathology has been excluded, time or a change to another formulation may solve the problem. Changing to an oral contraceptive with a higher estrogen content, while potentially useful in minimizing menstrual irregularity, should be done only if necessary since this may increase the risk of thromboembolic disease.

Use of oral contraceptives in the event of a missed menstrual period:

- 1. If the patient has not adhered to the prescribed schedule, the possibility of pregnancy should be considered at the time of the first missed period and oral contraceptive use should be discontinued if pregnancy is confirmed.
- 2. If the patient has adhered to the prescribed regimen and misses two consecutive periods, pregnancy should be ruled out.

More about Cyclafem 1 / 35 (ethinyl estradiol / norethindrone)

- · Check interactions
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- During pregnancy
- FDA approval history
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• Cyclafem 1/35 prescribing information

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DRUG STATUS

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Risk data available
CSA Schedule*
N/A Not a controlled drug
Approval History

Drug history at FDA

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5.0 / 10

20 Reviews

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