

...so close to nature ORACON®

16 White—Ethinyl Estradiol, 0.1 mg. Tablets; 5 Pink—Dimethisterone, 25 mg., and Ethinyl Estradiol, 0.1 mg. Tablets.

the first sequential oral contraceptive

Indication: To inhibit ovulation and provide an effective oral method of contraception.

Effectiveness: Oral contraceptives, including ORACON, are highly effective.

Contraindications: Because of estrogen content, ORACON is contraindicated in known or suspected malignancy of the breasts or reproductive tract, and in young women in whom epiphyseal closure is not complete. Do not use immediately postpartum in the nursing mother because of possible inhibition of lactation or estrogenic responses in the infant. Use is also contraindicated in presence of liver dysfunction or disease, and in patients with a history of thrombophlebitis, pulmonary embolism, or cerebral vascular accident.

Warnings: Use with caution in patients with cardiac or renal dysfunction. Patients with a history of psychic depression should be carefully observed and the drug discontinued if the depression recurs to a marked degree. Discontinue medication pending examination if there is sudden partial or complete loss of vision, or if there is sudden onset of proptosis, diplopia or migraine. If examination reveals papilledema or retinal vascular lesions, medication should be withdrawn.

Precautions: Because of insufficient evidence concerning the possible effects of ORACON in patients with a history of metabolic disease or conditions which might be aggravated by possible estrogen-induced fluid retention (such as epilepsy, migraine, asthma, and cardiac or renal disease), ORACON should be used with care in such patients. Pre-existing uterine fibroids may increase in size while using this product. Any effect of prolonged use on pituitary, ovarian, adrenal, hepatic, or uterine function awaits further studies. Discontinue before liver or endocrine function tests. Because of osteoblastic action

of estrogens, carefully observe patients with metabolic bone disease or renal disease while on ORACON. Since safety in pregnancy is not proven, any patient missing 2 consecutive periods should have pregnancy ruled out before continuing the regimen. An estrogen-induced increase in cervical mucus is frequent; patients should be so advised. Continuous use for more than 18 months is not recommended at this time. Recurring breakthrough bleeding, particularly after the first few cycles, should be reported to the physician for further investigation. As a special precaution, another method of contraception should be used during the first 7 tablet days of the first cycle, or following discontinuance of ORACON for one or more months.

Side Effects: Few undesirable side effects occur with ORACON. Only 4.4% of patients discontinued medication because of side effects during clinical trials. As expected with estrogen therapy, nausea was the side effect reported most frequently. Nausea, when it occurs, is usually during the first cycle and is not severe. It may be alleviated with continued therapy or by administration at bedtime, with meals, or in divided doses. Other side effects reported during clinical studies included vomiting, abdominal cramps, bloating, anorexia, malaise, breakthrough bleeding, changes in amount and/or duration of menstrual flow, mucorrhea, and amenorrhea; headache, increased and decreased libido, weight gain or loss, nervousness, breast tenderness, dizziness, edema, diarrhea, drowsiness and premenstrual tension. Two cases of thrombophlebitis were reported during clinical trials; however, a cause-and-effect relationship has not been established.

Administration: Counting onset of menses as Day 1, the patient starts med-

ication on Day 5 of the menstrual cycle and takes one white tablet daily from Day 5 through Day 20, then one pink tablet daily from Day 21 through Day 25.

The patient should follow the dosage schedule strictly. If the regimen is interrupted, for the fullest possible protection the patient should consult her physician about the use of an additional contraceptive method for the rest of the cycle (also see Precautions). Menses usually begin 2 to 4 days after the last pink tablet has been taken. The patient starts her new cycle of medication on Day 5. If flow does not occur by the 7th day after taking the last pink tablet start the next full course of therapy on that day, thus allowing 6 days without drug. In case of breakthrough bleeding: if spotting, continue medication; if menstrual flow, discontinue medication and begin a new full course on Day 5; for recurring breakthrough bleeding or amenorrhea, see Precautions.

Availability: Available as 16 white and 5 pink tablets. Each white tablet contains 0.1 mg. ethinyl estradiol; each pink tablet contains 25 mg. dimethisterone plus 0.1 mg. ethinyl estradiol. Complete details on ORACON are available on request from Mead Johnson Laboratories, Evansville, Indiana 47721.

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