Loestrin advertisement.

[s.l.]: [s.n.], 1972

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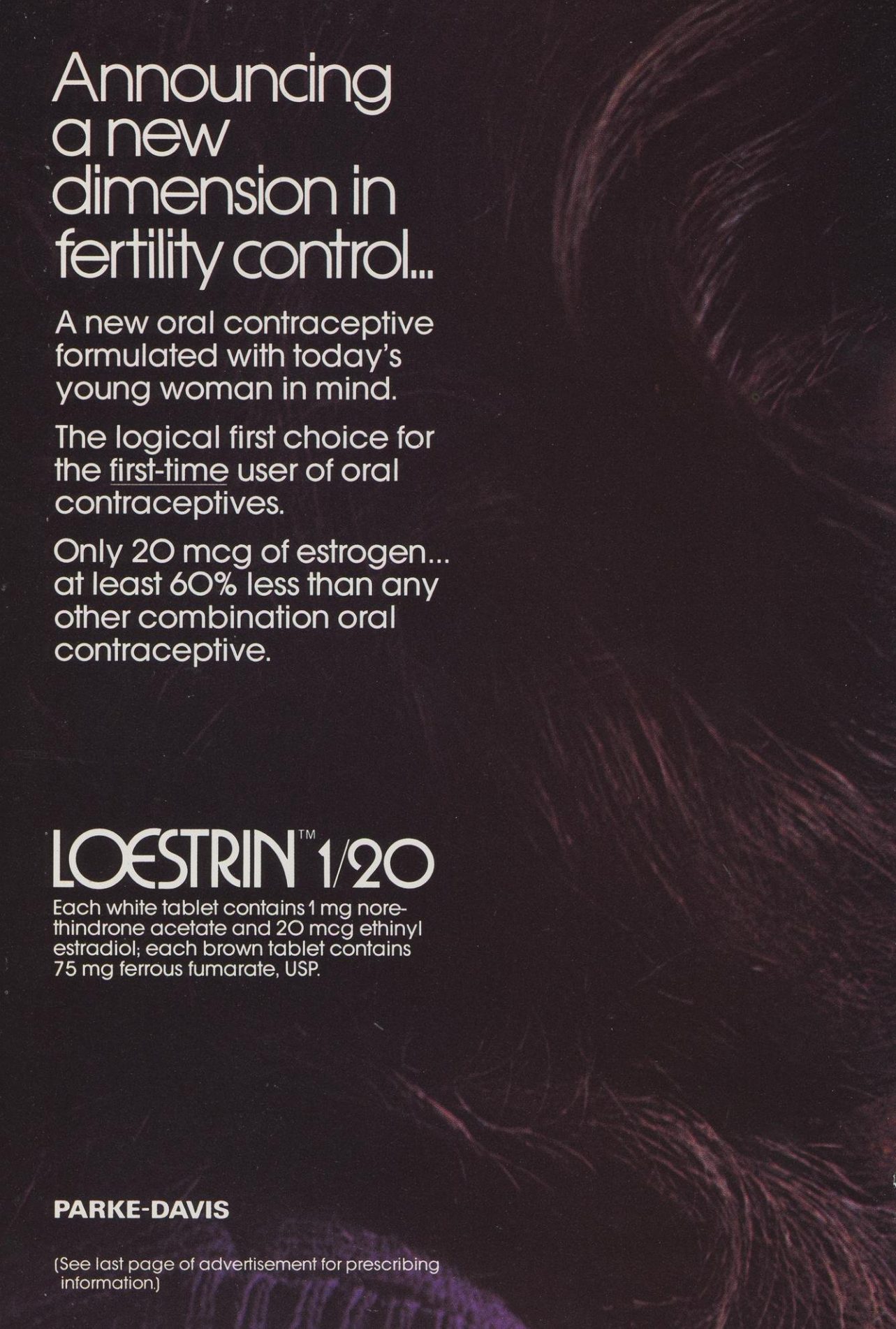
Announcing a new dimension in fertility control...
A new oral contraceptive formulated with today's young woman in mind.
The logical first choice for the first-time user of oral contraceptives.
Only 20 mcg of estrogen... at least 60% less than any other combination oral contraceptive.
LOESTRIN™ 1/20
Each white tablet contains 1 mg norethindrone acetate and 20 mcg ethinyl estradiol; each brown tablet contains 75 mg ferrous fumarate, USP.
PARKE-DAVIS
(See last page of advertisement for prescribing information.)

How much estrogen is enough?

Good therapeutics would indicate the use of the lowest effective dose of estrogen that is otherwise acceptable.

Theoretical safety of less estrogen

Clinical experience is not conclusive, but available data indicate a trend toward a higher risk of thromboembolic disorders with higher estrogen doses.

Theoretically, Loestrin 1/20 should be a safer product.

A high degree of contraceptive efficacy

In 12,241 cycles, only 10 pregnancies resulted—and 7 of these were due to patient failure.

While overall efficacy for Loestrin 1/20 is somewhat lower than that of the higher-dose combination products, both types provide almost completely effective contraception.

Wide patient acceptance

During clinical studies, there was a remarkably low incidence of side effects of the type usually attributed to too much estrogen. Typical of the low incidence of these estrogen-related side effects were: breast soreness (0.24%), nausea (1.24%), bloating (0.09%), and edema (0.02%).

As you might expect from the low estrogen content, some patients may experience bleeding irregularities. For patients who have unacceptable bleeding patterns, a higher-dose product may be required.

Convenient nonstop regimen

With Loestrin 1/20, there's no need for your patient to count days. One tablet a day, every day, provides convenient fertility control.

It's as simple as that.

The logical first choice for the first-time user

LOESTRIN 1/20

Each white tablet contains 1 mg norethindrone acetate and 20 mcg ethinyl estradiol; each brown tablet contains 75 mg ferrous fumarate, USP.

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Brief Summary of Prescribing Information

ACTIONS

Loestrin 1/20 achieves its contraceptive effect primarily by inhibition of ovulation through gonadotropin suppression. It is possible that other actions such as changes in cervical mucus and in the endometrium may contribute to the high efficacy of oral contraceptives.

SPECIAL NOTE

Oral contraceptives have been marketed in the United States since 1960. Reported pregnancy rates vary from product to product. The effectiveness of Loestrin 1/20 is somewhat lower than that of the higher-dose combination products. Both provide almost completely effective contraception.

The dropout rate for medical reasons, as observed in the clinical trials that were conducted with Loestrin 1/20, appears to be somewhat higher than observed with higher-dose combination products. This higher dropout rate was observed to be due particularly to irregular bleeding.

An increased risk of thromboembolic disease associated with the use of hormonal contraceptives has now been shown in studies conducted in both Great Britain and the United States. Other risks, such as those of elevated blood pressure, liver disease, and reduced tolerance to carbohydrates, have not been quantitated with precision.

Long-term administration of both natural and synthetic estrogens in subprimate animal species in multiples of the human dose increases the frequency for some animal carcinomas. These data cannot be transposed directly to man. The possible carcinogenicity due to the estrogens can neither be affirmed nor refuted at this time. Close clinical surveillance of all women taking oral contraceptives must be continued.

INDICATION

Loestrin 1/20 is indicated for the control of conception.

CONTRAINDICATIONS

1. Thrombophlebitis, thromboembolic disorders, cerebral apoplexy, or a past history of these conditions.
2. Markedly impaired liver function.
3. Known or suspected carcinoma of the breast.
4. Known or suspected estrogen-dependent neoplasia.
5. Undiagnosed abnormal genital bleeding.

WARNINGS

1. The physician should be alert to the earliest manifestations of thrombotic disorders (thrombophlebitis, cerebrovascular disorders, pulmonary embolism, and retinal thrombosis). Should any of these occur or be suspected, the drug should be discontinued immediately.

Retrospective studies of morbidity and mortality in Great Britain and studies of morbidity in the United States have shown a statistically significant association between thrombophlebitis, pulmonary embolism, and cerebral thrombosis and embolism and the use of oral contraceptives. There have been three principal studies in Britain[1-3] leading to this conclusion, and one[4] in this country. The estimate of the relative risk of thromboembolism in the study by Vessey and Doll[3] was about sevenfold, while Sartwell and associates in the United States found a relative risk of 4.4, meaning that the users are several times as likely to undergo thromboembolic disease without evident cause as nonusers. The American study also indicated that the risk did not persist after discontinuation of administration, and that it was not enhanced by long continued administration. The American study was not designed to evaluate a difference between products. However, the study suggested that there might be an increased risk of thromboembolic disease in users of sequential products. This risk cannot be quantitated, and further studies to confirm this finding are desirable.

2. Discontinue medication pending examination if there is sudden partial or complete loss of vision, or if there is a sudden onset of proptosis, diplopia, or migraine. If examination reveals papilledema or retinal vascular lesions, medication should be withdrawn.

3. Since the safety of Loestrin 1/20 in pregnancy has not been demonstrated, it is recommended that, for any patient who has missed two consecutive periods, pregnancy should be ruled out before continuing the contraceptive regimen. 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.

4. A small fraction of the hormonal agents in oral contraceptives has been identified in the milk of mothers receiving these drugs. The long-range effect to the nursing infant cannot be determined at this time.

PRECAUTIONS

1. The pretreatment and periodic physical examinations should include special reference to breasts and pelvic organs, including Papanicolaou smear, since estrogens have been known to produce tumors, some of them malignant, in five species of subprimate animals.

2. Endocrine and possibly liver function tests may be affected by treatment with Loestrin 1/20. Therefore, if such tests are abnormal in a patient taking Loestrin 1/20, it is recommended that they be repeated after the drug has been withdrawn for two months.

3. Under the influence of estrogen-progestogen preparations, preexisting uterine fibromyomata may increase in size.

4. Because these agents may cause some degree of fluid retention, conditions which might be influenced by this factor, such as epilepsy, migraine, asthma, cardiac or renal dysfunction, require careful observation.

5. An alteration in menstrual patterns in many patients is likely to be induced by using Loestrin 1/20. The amount and duration of flow and cycle length may be variable. Because of these irregular bleeding patterns, it is important that the physician take this into consideration when attempting to determine if persistent bleeding is from organic causes.

6. Patients with a history of psychic depression should be carefully observed and the drug discontinued if the depression recurs to a serious degree.

7. Any possible influence of prolonged Loestrin 1/20 therapy on pituitary, ovarian, adrenal, hepatic, or uterine function awaits further study.

8. A decrease in glucose tolerance has been observed in a significant percentage of patients on oral contraceptives. The mechanism of this decrease is obscure. For this reason, diabetic patients should be carefully observed while receiving Loestrin 1/20 therapy.

9. The age of the patient constitutes no absolute limiting factor, although treatment with Loestrin 1/20 may mask the onset of the climacteric.

10. The pathologist should be advised of Loestrin 1/20 therapy when relevant specimens are submitted.

11. Susceptible women may experience an increase in blood pressure following administration of contraceptive steroids.

ADVERSE REACTIONS OBSERVED IN PATIENTS RECEIVING ORAL CONTRACEPTIVES

A statistically significant association has been demonstrated between use of oral contraceptives and the following serious adverse reactions:

Thrombophlebitis
Cerebral thrombosis
Pulmonary embolism

Although available evidence is suggestive of an association, such a relationship has been neither confirmed nor refuted for the following serious adverse reactions:

Neuro-ocular lesions, eg, retinal thrombosis and optic neuritis

The following adverse reactions are known to occur in patients receiving oral contraceptives:

- Nausea
- Vomiting
- Gastrointestinal symptoms (such as abdominal cramps and bloating)
- Breakthrough bleeding
- Spotting
- Change in menstrual flow
- Amenorrhea during and after treatment
- Edema
- Chloasma or melasma
- Breast changes: tenderness, enlargement, and secretion
- Change in weight (increase or decrease)
- Changes in cervical erosion and cervical secretions
- Suppression of lactation when given immediately postpartum
- Cholestatic jaundice
- Migraine
- Rash (allergic)
- Rise in blood pressure in susceptible individuals
- Mental depression

Although the following adverse reactions have been reported in users of oral contraceptives, an association has been neither confirmed nor refuted:

- Anovulation post-treatment
- Premenstrual-like syndrome
- Changes in libido
- Changes in appetite
- Cystitis-like syndrome
- Headache
- Nervousness
- Dizziness
- Fatigue
- Backache
- Hirsutism
- Loss of scalp hair
- Erythema multiforme
- Erythema nodosum
- Hemorrhagic eruption
- Itching

The following laboratory results may be altered by the use of oral contraceptives:

- Hepatic function: increased sulfobromophthalein retention and other tests
- Coagulation tests: increase in prothrombin, factors VII, VIII, IX, and X
- Thyroid function: increase in PBI and butanol extractable protein bound iodine, and decrease in T^3 uptake values
- Metyrapone test
- Pregnanediol determination

1. Royal College of General Practitioners: Oral contraception and thromboembolic disease. J Coll Gen Pract 13:267, 1967.
2. Inman WHW, Vessey MP: Investigation of deaths from pulmonary, coronary and cerebral thrombosis and embolism in women of child-bearing age. Brit Med J 2:193, 1968.
3. Vessey MP, Doll R: Investigation of relation between use of oral contraceptives and thromboembolic disease. A further report. Brit Med J 2:651, 1969.
4. Sartwell PE, Masi AT, Arthes FG, Greene GR, Smith HE: Thromboembolism and oral contraceptives: An epidemiological case–control study. Am J Epidem 90:365, 1969.

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PARKE, DAVIS & COMPANY, Detroit, Michigan 48232