Summary of prescribing information

Functional Uterine Bleeding

Recommended Treatment. For emergency control of severe bleeding in menorrhagia or metrorrhagia, 20 to 30 mg. of ENOVID should be given until the bleeding is controlled. Usually the daily dose may then be reduced to 10 mg. daily and continued through day 24 of the cycle. The drug is then discontinued and the patient will usually menstruate approximately three days later.

Following treatment of this initial cycle the patient should be given 5 to 10 mg. of ENOVID daily from day 5 through day 24 of the next two or three cycles.

Ovulation Control

ENOVID has been shown in extensive studies to be extremely effective in inhibiting ovulation. For additional information the physician is referred to The Physicians' Product Brochures: *Enovid-E for Contraception,* No. 62, and *Enovid,* No. 67, which are available from G. D. Searle & Co. upon request.

Recommended Treatment. ENOVID-E or one 5-mg. ENOVID tablet should be prescribed daily for twenty days beginning on day 5 of the cycle, counting the first day of menstruation as day 1. Patients so treated will usually menstruate on day 28.

Dysmenorrhea

Patients with primary dysmenorrhea usually are relieved by inhibiting ovulation.

Recommended Treatment. A daily dose of 5 mg. should be given from day 5 of the cycle through day 24. The drug is then discontinued and the patient will usually menstruate approximately three days later. Two or three additional cycles are treated in the same manner and therapy interrupted to determine the need for further treatment.

Premenstrual Tension

Although ENOVID may be used for the treatment of premenstrual tension and may prove successful, an aggravation of premenstrual tension occurs occasionally, presumably as a result of sodium retention.

Recommended Treatment. The dose of ENOVID is 5 mg. daily from day 5 through day 24. The treatment should be repeated for three consecutive cycles.

Primary and Secondary Amenorrhea

If no physical cause for amenorrhea is found, it is possible to provide regular withdrawal bleeding closely resembling a normal menstrual period with ENOVID therapy. In both types of amenorrhea, it is known that a course of ENOVID treatment may be followed by resumption of normal menstruation.

Recommended Treatment. One 5-mg. tablet of ENOVID should be given daily for ten days to establish a cycle, and then 5 mg. daily from day 5 through day 24 for two consecutive cycles. Dosage should be increased for a few days if breakthrough bleeding occurs. The drug should be omitted after the third cyclic course to determine the need for further therapy.

Idiopathic Infertility

It has been suggested that infertile women with no detectable abnormality may be subject to endometrial hypoplasia with consequent dysfunction of the uterus or tubes. ENOVID may be prescribed in order to stimulate endometrial development in the natural sequence.

Recommended Treatment. One 5-mg. tablet of ENOVID is administered daily from day 5 for twenty days. If breakthrough bleeding occurs, the dosage should be repeated for three consecutive cycles. Conception should then be attempted in the immediate following cycles, around the expected time of ovulation. Ovulation in the first cycle after treatment may be delayed for three to five days or even longer; subsequent cycles will usually revert to the duration previously typical for the individual patient.

Endometriosis

Recommended Treatment. A daily dose of ENOVID should be given for six to nine months or more on the following schedule: 5 mg. should be given for two weeks beginning on day 5 of a menstrual cycle. This daily dose should be given continuously without cyclic interruption and increased 5 mg. every two weeks until the patient is receiving 20 mg. daily. This daily dose of 20 mg. should be continued for six to nine months and should be further increased (up to 40 mg. daily) if breakthrough bleeding occurs.

Therapy may be discontinued if the disease is mild and the lesions are no longer palpable after six months. When the condition is more severe it will be necessary to continue treatment for nine months longer.

Recurrent and Threatened Abortion

ENOVID results in endometrial changes which closely mimic the normal endometrium of pregnancy and has been well demonstrated to maintain the integrity of the endometrium over prolonged periods. It should be borne in mind that in threatened abortion the first signs are frequently late in the actual condition. For this reason, the re-establishment of endometrial integrity may be very difficult or impossible by the application of any known method.

Recommended Treatment. Recurrent Abortion. A daily dosage of 20 mg. of ENOVID is started as soon as pregnancy is suspected. If the gonadotropin pregnancy test is positive the dosage should be continued to term or at least until the end of the fifth month of pregnancy. If spotting occurs during pregnancy this dosage may be increased to 40 to 50 mg. daily until the bleeding stops.

Threatened Abortion. Treatment must be started before the abortion has reached an advanced stage. From 20 to 30 mg. daily is given for seven to ten days and then 10 to 20 mg. daily until term. If the symptoms of impending abortion reappear the dosage should be increased immediately until the symptoms disappear.

Infertility Due to Inadequate Luteal Phase

Recommended Treatment. Three days after ovulation 5 mg. of ENOVID is given daily and continued through at least five months of the pregnancy if a gonadotropin test reveals that the patient is pregnant. If the test is negative, ENOVID should be discontinued and similar therapy employed in a subsequent cycle.

Adjustment of the Menses

Recommended Treatment. To *postpone* the menses 10 mg. of ENOVID should be given daily, beginning at any time up to a week before the expected menstruation. This dose will delay menstruation for periods up to two weeks; for longer delays the daily dose should be increased to 20 mg. The drug may be discontinued at any desired time, and the menstrual flow may be expected about three days later.