

Hydroxyprogesterone

Injection 250mg

Effectively meet the requirement in conditions like

- *Threatened and Habitual Abortion.*
- *Primary and Secondary Amenorrhea.*
- *Infertility due to Corpus Luteum Insufficiency.*
- *Post Operative Endometrial Cancer.*

BRIEF PRESCRIBING INFORMATION:

COMPOSITION: 1 ml hydroxyprogesterone contains 250 mg hydroxyprogesterone caproate in oily solution.
INDICATIONS: Habitual and threatened abortion, infertility due to corpus luteum insufficiency, primary and secondary amenorrhoea, Post operative endometrial cancer. **DOSEAGE AND ADMINISTRATION:** Like all oily solutions hydroxyprogesterone must be injected intramuscularly. Experience shows that the short lasting reactions (urge to cough, coughing fits, respiratory distress) which occur in very rare cases during or immediately after the injection of oily solutions can be avoided by injecting the solution extremely slowly. **Abortion:** Medical therapy should be given in early pregnancy only if it is absolutely essential. This is also valid for the use of hormone preparations such as hydroxyprogesterone for the maintenance of pregnancy consequently, Hydroxyprogesterone should only be prescribed if there is an urgent desire for children - primarily in the presence of corpus luteum insufficiency or a history of abortion. Hydroxyprogesterone is indicated for both prophylaxis and treatment of abortion because it compensates for the hormone deficit, induces quiescence of the uterus and stimulates growth of an underdeveloped uterus. Prolonged treatment with an adequate dosage of hydroxyprogesterone is necessary to achieve this objective and to maintain pregnancy. Because hydroxyprogesterone places the uterus at rest, it is possible for an already dead embryo to be retained. In the case of protracted therapy, it is therefore necessary to check the continued existence of pregnancy by means of appropriate examinations and immunological tests. **Infertility due to corpus luteum insufficiency:** Cases in which the luteal phase is short: a situation characterized by too short-lived an increase in the basal body temperature in the second half of the cycle-hydroxyprogesterone brings about secretory transformation of the inadequately transformed endometrium, thus improving the chances of nidation. Intramuscular injection of 250 mg Hydroxyprogesterone about 3 days after the rise in basal body temperature. Since there is often a coexisting estrogen deficit, additional intramuscular injection of estrogen 10 mg. Thus a physiological transformation of the endometrium can be achieved. **Primary and secondary amenorrhoea:** In the case of secondary amenorrhoea hormonal treatment is to be given at the earliest 8 weeks after the last menstrual period. In order to induce a menstruation-like bleeding, an estrogen 10 mg is to be given before the administration of hydroxyprogesterone. **Commencement of treatment:** On the first day of treatment 2 ampoules of estrogen 10mg intramuscularly, 14 days later 1 ampoule of estrogen 10 mg together with 250 mg Hydroxyprogesterone I.M. Withdrawal bleeding starts: about the 28th day of treatment. **Continuation of treatment:** (over at least 2-3 cycles) On the 6th day of the artificial cycle, 1 ampoule of estrogen 10 mg intramuscularly and on the 16th day another ampoule of estrogen 10 mg together with 250 mg hydroxyprogesterone intramuscularly (1st day of bleeding = 1st day of the cycle). An attempt can then be made to stop the estrogen treatment, and to induce a cyclical bleeding by an intramuscular injection of 250 mg Hydroxyprogesterone between the 16th and the 20th day of cycle. **3rd cycle:** (over 3 cycles) Cyclical treatment: 1 ampoule of estrogen 10 mg I.M. following menstruation, on the 6th day of the cycle, and 250 mg Hydroxyprogesterone together with 1 ampoule of estrogen 10 mg I.M. on the 16th day of the cycle. The treatment must be given over several cycles. Induction of a state of pseudo-pregnancy: Treatment is started following a menstruation, on the 5th day of cycle, 1st to 6th week: 1-2 ampoules of estrogen 10 mg together with 250 mg Hydroxyprogesterone I.M. weekly, 7 week: 1-2 ampoules of estrogen 10 mg together with 250 mg hydroxyprogesterone I.M. 8th week: 200 mg hydroxyprogesterone I.M. After the 6-weeks therapy a withdrawal bleeding will occur. **CONTRAINDICATIONS:** A history of herpes of pregnancy, previous or existing liver tumours. **Presentation:** Pack of 3's injection in a pack.



Zafa Pharmaceutical Laboratories (Private) Ltd.
L-1/B, Block-22, FEDERAL 'B' INDUSTRIAL AREA, KARACHI-75950 (PAKISTAN)
Email: zafaph@cybernet.pk, Website: www.zafa.com.pk



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Light of hope



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Threatened Abortion:

... with weekly I.M. Injection of 17 alpha - hydroxyprogesterone caproate delivery had been postponed in 21 out of 24 patients.

Reference:

Kauppila A et al, Suppression of threatened premature labor by administration of cortisol and 17-alpha-hydroxyprogesterone caproate: a comparison with ritodrine. *Am J obstet gynecol* 1980 oct 15; 138 (4) : 404-8 Related Articles, Books, Link out.

No adverse Effect on Final outcome of Pregnancy:

There was no evidence that hydroxyprogesterone caproate had any adverse effect on the infant or the final outcome of pregnancy.

Reference:

Varma TR et al, evaluation of the use of hydroxyprogesterone hexanoate in early pregnancy. *Int J Gynaecol obstet* 1982 Feb; 20 (1) : 13-7 Related Articles, Books, Linkout.

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Infertility Due to Corpus Luteum Insufficiency:

... 17 - alpha - Hydroxyprogesterone caproate preparation for better acceptance appear to be the most suitable and comfortable method for luteal phase support.

Reference:

Abate A et al, 17 - Alpha - Hydroxyprogesterone caproate and natural progesterone in assisted reproduction: a comparative study. *Clin Exp Obstet gynecol* 1980 oct 15; 138(4): 404-8 Related Articles, Books, Link out.

In Endometrial Carcinoma:

Adjuvant progestagen therapy in post operative endometrial cancer. The group of patients who received progestagens had significantly longer survival than the control group without hormone therapy.

Reference:

Urbanski K et al, Adjuvant progestagen therapy improves survival in patients with endometrial cancer after hysterectomy, *Eur J Gynaecol Oncol* 1993;14 Suppl: 98-104 Related Articles, Books, Linkout.