HALD

COMPOSITION: Each soft gelatin capsule contains:Natural Micronized progesterone100mg/200mg/300mg. Excipients. q.s. THERAPEUTIC INDICATIONS: Infertility & pregnancy, Luteal support during assisted reproductive techniques (ART). To provide luteal support in luteal phase defects. Threatened abortion / recurrent abortion with proven luteal phase insufficiency/ defects, Oocyte donation programme, To prevent preterm delivery. Menstrual Irregularities: As progesterone challenge test in secondary amenorrhoea. Dysfunctional uterine bleeding (DUB), Postmenstrual syndrome. Prevention of endometrial hyperplasia in non-hysterectomised postmenopausal women who are receiving estrogen as Hormone Replacement Therapy (HRT). DOSAGE AND ADMINISTRATION: The dosage regimen can be followed depending on the indication. Lower dose is required when vaginal route is used. Vaginal Administration Each capsule should be inserted deeply into the vagina. Rectal administration should be considered whenever vaginal administration is not possible. Luteal support during assisted reproductive techniques (IVF- ET) : HALD 200 mg thrice a day from the day of embryo transfer till pregnancy is confirmed. If pregnant, it is continued till 12th week of pregnancy.To provide luteal support in luteal phase defects: HALD 100 mg thrice a day from the 17th day of the cycle for 10 days. If pregnant, it is continued till 12th week of pregnancy. Threatened abortion / recurrent abortion with proven luteal phase insufficiency/defects: HALD 100 mg thrice a day till 12th week of pregnancy. Oocyte donation programme: 100 mg thrice daily from the day of embryo transfer till pregnancy is confirmed. If pregnant it is continued till 12th week of pregnancy. Prevent preterm delivery: HALD 100 mg administered once daily at bedtime from 24th to 34th week of pregnancy Oral Administration: The evening dose/once daily dose is preferably taken at bedtime. Secondary amenorrhoea: HALD 400 mg daily at bedtime for 10 days. Dysfunctional uterine bleeding (DUB): HALD 300 mg once daily from 12th day of the cycle for 10 days. Postmenopausal women with intact uterus (in addition to estrogen treatment): HALD 200 mg at bed time for 12 days sequentially per 28 day cycle. Premenstrual syndrome: HALD 100-200 mg once daily from 14th day of the cycle for 10 days. CONTRAINDICATIONS: Individuals known hypersensitivity to its ingredients. Undiagnosed abnormal genital bleeding. Known, suspected, or history of cancer of the breast. Active deep vein thrombosis, pulmonary embolism or history of these conditions. Active or recent (e.g., within the past year) arterial thromboembolic disease (e.g. stroke, myocardial infarction). Liver dysfunction or disease. USE IN SPECIAL POPULATION: Pregnancy: Reproductive studies performed in mice reveal no evidence of impaired fertility or harm to the fetus due to natural progesterone Lactation: Caution should be exercised when micronized progesterone capsules are administered to a nursing woman. Pediatric patient: Not recommended in pediatric population. WARNINGS : Cardiovascular disorders- An increased risk of pulmonary embolism, deep vein thrombosis (DVT), stroke, and myocardial infarction has been reported with estrogen plus progestin therapy. Should any of these occur or be suspected, estrogen with progestin therapy should be discontinued immediately. Breast cancer-Observational studies have reported an increased risk of breast cancer after estrogen plus progestin therapy. Probable dementia-Observational studies have reported an increased risk of dementia after estrogen plus progestin therapy. Rare instances of syncope and hypotension of possible orthostatic origin may occur. PRECAUTIONS: Fluid Retention: Progesterone may cause some degree of fluid retention. Women with conditions that might be influenced by this factor, such as cardiac or renal dysfunction, warrant careful observation. Dizziness and Drowsiness: Progesterone may cause transient dizziness and drowsiness and should be used with caution when driving a motor vehicle or operating machinery.Undiagnosed vaginal bleeding, diabetic patients and patients with history of clinical depression should be carefully observed.Vaginal administration is not recommended. If barrier methods of contraception are used, In patient with vaginal infection or recurrent cystitis, In patients who have recently given birth. Rectal administration is advisable in this group of patients. DRUG INTERACTIONS: Drugs known to induce the hepatic CYP450-3A4 such as barbiturates, anti-epileptic agents (phenytoin, carbamazepine), rifampicin, phenylbutazone, spironolactone, griseofulvin, some antibiotics (ampicillins, tetracyclines) and also herbal products containing St. John's wort, (Hypericum perforatum) may increase metabolism and the elimination of progesterone. the contrary ketokonazole and other inhibitors of CYP450-3A4 such as ritonavir and nelfinavir may increase bioavailability of progesterone. The metabolism of progesterone by human liver microsomes was inhibited by ketoconazole (IC50 <0.1 μM). Progesterone may interfere with the effects of bromocriptine and may raise the plasma concentration of ciclosporin. Progesterone may affect the results of laboratory tests of hepatic and/or endocrine functions. ADVERSE REACTIONS: Natural micronized progesterone is devoid of oestrogenic, androgenic and mineralocorticoid side effects. Common adverse effects are drowsiness, dizziness, breast tenderness and abdominal bloating. Side effects are less when vaginal route is used. Vaginal irritation is the most common side effect with vaginal use. OVERDOSAGE: This is unlikely and is not expected to produce any major adverse effects. Patient should be observed and, if necessary, symptomatic and supportive measures should be provided. (For details, please refer full prescribing information)

(For the use of a registered medical practitioner or hospital or laboratory only)