**HALD INJ**

COMPOSITION: 1 ml ampoule contains : Natural Micronized progesterone 100 mg Excipients.q.s.2 ml ampoule contains: Natural Micronized progesterone 200 mg. Excipients. q.s.THERAPEUTIC INDICATIONS: Amenorrhea: For progesterone withdrawal test in endocrinal evaluation of a case of secondary amenorrhoea (where pregnancy is ruled out) to judge oestrogen priming. For the treatment of dysfunctional uterine bleeding: Abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as submucous fibroids or uterine cancer.—not much used.For the maintenance of early pregnancy: In cases of documented history of repeated miscarriages due to luteal phase defect and as an adjunct to successful treatment of infertility with ART techniques. For threatened abortion: Maintenance of early pregnancy DOSAGE AND ADMINISTRATION: Progesterone is administered as intramuscular injection. Progesterone injection may cause irritation at the site of injection. Secondary amenorrhoea: Progesterone withdrawal test in endocrinal evaluation of a case of secondary amenorrhoea to judge oestrogen priming 50 –100 mg/day for 3-6 consecutive days. (after pregnancy is ruled out) Dysfunctional uterine bleeding: 5-10 mg daily given for five to ten consecutive days until 2 days before anticipated onset of menstruation. Other oral progestins are used for Dysfunctional uterine bleeding.Maintenance of early pregnancy with history of repeated miscarriages: Twice weekly or more frequent (maximum: daily) injections of 25-100 mg from approximately day 15 until 12-14 weeks of pregnancy. Adjunct to successful treatment of infertility with ART techniques.CONTRAINDICATIONS: Known hypersensitivity to progesterone or any of the inactive ingredients, Thrombophlebitis, History of thromboembolic disorders , Cerebral haemorrhage, Marked hepatic dysfunction, Known or suspected malignancies of the breast or genital tract. Undiagnosed vaginal bleeding, As a diagnostic test for pregnancy, Missed abortion. USE IN SPECIAL POPULATION: Pregnancy: HALD is used to maintain pregnancy where there is deficient production of endogenous progesterone. It is natural progesterone; therefore it is not associated with masculinization of a female foetus as are synthetic progestins. It should be discontinued once there is adequate secretion of placental progesterone. Lactation: It should be administered to lactating mothers only if the potential benefit to the lactating mother outweighs any potential risk to the suckling infant. Pediatric patient: Not recommended in pediatric population .WARNINGS AND PRECAUTIONS: This medication should be used cautiously in patients with Conditions that might be aggravated by fluid retention (eg. hypertension, cardiac disease, renal disease, epilepsy). With a history of mental depression, diabetes, mild to moderate hepatic dysfunction, acute intermittent porphyria, migraine or photosensitivity. If unexplained, partial or complete loss of vision, , retinal vascular lesions or migraine occur during therapy, discontinue the drug. The physician should be alert to the earliest manifestation of thrombophlebitis and pulmonary embolism in patients taking progestogens. In cases of undiagnosed vaginal bleeding, adequate diagnostic measures are indicated. Progesterone may affect the results of laboratory tests of hepatic and/or endocrine functions. Progesterone at high doses is an antifertility. DRUG INTERACTIONS: Drugs No potentially hazardous interactions have been reported. It may raise the plasma concentration of cyclosporin. . Ketoconazole or other known inhibitors of cytochrome may increase the bioavailability of progesterone. ADVERSE REACTIONS: The following adverse reactions have been observed in women taking progesterone: Breakthrough bleeding, spotting, change in menstrual flow, amenorrhoea, edema. Change in weight (increase or decrease), catabolism. Changes in cervical erosion and cervical secretions, breast changes, cholestatic jaundice, rash (allergic), acne, chloasma, nausea, alopecia, hirsutism, mental depression, pyrexia, insomnia, somnolence and local reactions at the site of injection. 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)