AQUAGEST-

AQUAGEST- progesterone solution for injection Composition: Each ml contains: Progesterone IP 22.35 mg Water for Injections IP q.s. to 1 ml Indication: It is indicated in adults for luteal support as part of an Assisted Reproductive Technology (ART) treatment program in infertile women who are unable to use or tolerate vaginal preparations. Dosage Adults Once daily injection of 25 mg from day of oocyte retrieval, usually until12 weeks of confirmed pregnancy. It is administered by subcutaneous (25 mg) or intramuscular (25 mg) route. Dosage recommendations for children and the elderly are not appropriate because indications for injection 25 mg are restricted to women of child-bearing age. Method of administration :Treatment with AQUAGEST should be initialed under the supervision of a physician experienced in the treatment of fertility problems .For Subcutaneous administration Choose an appropriate area (front of thigh,lower abdomen), swab that area, pinch firmly the skin together and insert the needle at anangle of 45° to 90°. The product should be injected slowly to minimize local tissue damage. Intramuscular administration: Choose an appropriate area {femoral quadriceps of the right or left high).Swab proposed area, insert a deep injection {needle at an angle of 90°). The product should be injected slowly to minimize local tissue damage. Contraindications It should not be used in individuals with any of the following conditions: • Known missed abortion or ectopic pregnancy • Hypersensttivity to progesterone or to any of the excipienls • Undiagnosed vaginal bleeding • Severe hepatic dysfunction or disease •A history of idiopathic jaundice severe pruritus or pemphigoid gestation during pregnancy. • Known or suspected breast or genital tract cancer •Active arterial or venous thromboembolism or severe thrombophlebitis, or a history of these event • Porphyria. Warning and precaution: AQUAGEST should be discontinued if any of the following conditions are suspected: myocardial infarction, cerebrovascular disorders, arterial or venous thromboembolism, thrombophlebitis, or retinal thrombosis, in smokers, in users >35 years, and in those with risk factors for atherosclerosis. Caution is indicated in patients with mild to moderate hepatic dysfunction, epilepsy, migraine, asthma, cardiac or renal dysfunction. Patients with a history of depression should be closely observed &discontinue Aquagest if symptoms worsen. Diabetic patients should be carefully observed while receiving progesterone therapy because a decrease in insulin sensitivity and in glucose tolerance has been observed in some patients. In case of transient ischemic events, appearance of sudden severe headaches, or vision impairments related to papillary oedema or retinal hemorrhage its use should be discontinued. Pregnancy & lactation: AQUAGEST is indicated for luteal support as part of an ART treatment program in infertile women. The rates of spontaneous abortion, congenital anomalies and ectopic pregnancies observed during the clinical trial were comparable with the event rate described in the general population. Progesterone is excreted in human milk and AQUAGEST should not be used during breast-feeding Adverse drug reactions: Administration site reactions, such as irritation, pain, pruritus and swelling, breast tenderness, breast pain, vaginal discharge, vulvo-vaginal pruritus, vulvo-vaginal discomfort, vulvo-vaginal inflammation. Other adverse reactions: abdominal distension, abdominal pain, nausea, vomiting, constipation, headache, OHSS, injection site haematoma, fatigue. Menstrual disturbances, premenstrual like syndrome, urticaria, acne, hirsutism, alopecia, depression, insomnia, jaundice, weight gain, anaphylactoid reactions are described with other drugs in this class of medicines

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