PRESCRIBING INFORMATION FOR LUBION(PROGESTERONE) 25 MG SOLUTION FOR INJECTION

Refer to Summary of Product Characteristics (SmPC) for full information.

PRESENTATION:

Progesterone 25 mg Solution for Injection.

INDICATION:

Lubion 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 & ADMINISTRATION:

Once daily injection of 25 mg from day of oocyte retrieval, usually until 12 weeks of confirmed pregnancy. Lubion is given by subcutaneous or intramuscular injection. Treatment should be initiated under the supervision of a physician experienced in the treatment of fertility problems. Children and the Elderly: As the indications for Lubion are restricted to women of child-bearing age, dosage recommendations for children and the elderly are not appropriate. Renal and Hepatic impairment: No experience in these patients.

CONTRAINDICATIONS:

Hypersensitivity to progesterone or to any of the excipients; undiagnosed vaginal bleeding; known missed abortion or ectopic pregnancy; severe hepatic dysfunction or disease; known or suspected breast or genital tract cancer; active or history of, arterial or venous thromboembolism or severe thrombophlebitis; porphyria; history of idiopathic jaundice, severe pruritus or pemphigoid gestationis during pregnancy.

WARNINGS & PRECAUTIONS:

Lubion should be discontinued if any of the following conditions are suspected: myocardial infarction, cerebrovascular disorders, arterial or venous thromboembolism, thrombophlebitis, or retinal thrombosis. Caution indicated in patients with mild to moderate hepatic dysfunction. Close observation required in patients with a history of depression (discontinue if symptoms worsen) and in patients with conditions that could be influenced by fluid retention (e.g. epilepsy, migraine, asthma, cardiac or renal dysfunction). Diabetic patients should be carefully observed (see Interactions section below). Sex steroid use may increase the risk of retinal vascular lesions, caution should therefore be taken in users >35 years, in smokers, and in those with risk factors for atherosclerosis. Use should be terminated in case of transient ischemic events, appearance of sudden severe headaches, or vision impairments related to papillary oedema or retinal haemorrhage. Abrupt discontinuation of progesterone dosing may cause increased anxiety, moodiness, and increased sensibility to seizures. Before starting treatment with Lubion, the patient and her partner should be assessed by a doctor for causes of infertility or pregnancy complications.

INTERACTIONS:

Drugs known to induce the hepatic CYP3A4 system (e.g. rifampicin, carbamazepine, griseofulvin, phenobarbital, phenytoin or St. John's Wort) may increase the elimination rate and thereby decrease the bioavailability of progesterone. Ketoconazole and other inhibitors of CYP3A4 decrease elimination rate and thereby increase the bioavailability of progesterone. Progesterone can influence diabetic control and so an adjustment in antidiabetic dosage could be required (see section Warnings and Precautions). Progestogens may inhibit ciclosporin metabolism leading to increased

plasmaciclosporin concentrations and a risk of toxicity. The effect of concomitant injectable products on the exposure of progesterone from Lubion has not been assessed. Concomitant use with other drugs is not recommended.

FERTILITY, PREGNANCY & LACTATION:

Lubion is used in the treatment of some forms of infertility and as part of an ART treatment programme. Limited and inconclusive data is available on the risk of congenital anomalies following intrauterine exposure during pregnancy. The rates of congenital anomalies, spontaneous abortion and ectopic pregnancies observed during the clinical trial were comparable with the event rate described in the general population although the total exposure is too low to allow conclusions to be drawn. Progesterone is excreted in human milk and Lubion should not be used during breast-feeding.

UNDESIRABLE EFFECTS:

Very common (≥ 1/10): uterine spasm; vaginal haemorrhage; administration site reactions. Common (≥ 1/100 to <1/10): Headache; abdominal distension; abdominal pain; nausea; vomiting; constipation; breast tenderness; breast pain; vaginal discharge; vulvo-vaginal pruritus; vulvo-vaginal discomfort; vulvo-vaginal inflammation; OHSS; injection site haematoma; injection site induration; fatigue. Uncommon (≥1/1000 and <1/100): Mood altered; dizziness; somnolence; gastrointestinal disturbances; pruritus; rash; breast disorders; feeling hot; malaise; pain. Refer to the SmPC for details on full side effect profile and interactions, including class effects.

BASIC NHS PRICE:

£56.00 per pack of 7 vials.

LEGAL CLASSIFICATION:

POM.

Marketing Authorisation number:

PL 21039/0026. Further information is available from Pharmsure Ltd, Sullivan House, 4-6 Colonial Business Park, Colonial Way, Watford WD24 4PR

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