Gestone® 50 mg/ml solution for intramuscular injection prescribing information.

Please consult summary of product characteristics (SmPC) before prescribing.

Name and active ingredients: Gestone® (Progesterone 50 mg/ml). Each 2 ml ampoule contains 100 mg of progesterone. **Indication**: Maintenance of early pregnancy in cases of documented history of 3 or more prior consecutive unexplained miscarriages and in selected cases as an adjunct to successful treatment of infertility with techniques such as in- vitro fertilisation (IVF) or gamete intra-fallopian transfer (GIFT) in order to facilitate uterine implantation of the fertilised ovum. **Dosage and administration:** Maintenance of pregnancy - Twice weekly or more frequent (maximum: daily) injections of 25-100 mg from approximately day 15, or day of transfer of embryo or gametes usually until 8 - 16 weeks of pregnancy when secretion of progesterone from the placenta should be established. Daily dosage can be increased to 200 mg at the discretion of the physician. **Contraindications**: Hypersensitivity to progestins, undiagnosed vaginal bleeding, missed or incomplete abortion, mammary or genital tract carcinoma, thrombophlebitis, cerebral haemorrhage, marked hepatic dysfunction. Contraindicated as a diagnostic test for pregnancy **Special warnings and precautions for use:** Use with caution in patients with conditions that might be aggravated by fluid retention (e.g. 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 any unexplained, loss of vision, proptosis or diplopia, papilloedema, retinal vascular lesions or migraine occur during therapy, Gestone® should be discontinued and appropriate diagnostic and therapeutic measures instituted. Gestone® contains benzyl alcohol which may cause allergic reactions. Gestone® is not recommended for use in patients that are breastfeeding or those with liver or kidney disease. **Interactions**: Gestone® may raise the plasma concentration of cyclosporin, can interfere with the effects of bromocriptine and affect the results of laboratory tests of hepatic and endocrine function **Undesirable effects:** *Frequency not known (cannot be estimated from the available data)*: Nausea, injection site reaction, oedema, pyrexia, cholestatic jaundice, allergic reaction, weight gain, catabolism increased, insomnia, depression (mental), somnolence, amenorrhoea, breakthrough bleeding. Menstrual flow altered, erosion and ectropion of the cervix, cervical discharge, breast fibrocystic changes, acne, alopecia, chloasma, hirsutism, rash. **Legal Category**: POM **Presentation and Basic NHS Price:** Gestone® 50 mg/ml- £100.00 10 x 2 ml ampoules. **Marketing authorisation (MA) number**: PL 05827/0025 **MA holder**: Nordic Pharma Limited, Building 1410, Arlington Business Park Theale, Reading RG7 4SA United Kingdom **Date of revision**: December 2025 **Item code:** UK-GEST-25-00014

Adverse events should be reported. Reporting forms and information can be found at yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Nordic Pharma at medinfo.uk@nordicpharma.com