SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Gestone 100mg/2ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient

Each ampoule contains Progesterone BP, 100mg in 2ml.

3. PHARMACEUTICAL FORM

Ampoules containing a pale yellow oily sterile solution of Progesterone for injection.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Gestone is indicated for the treatment of dysfunctional uterine bleeding.

It is also indicated for the 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.

4.2 Posology and method of administration

Dysfunctional uterine bleeding
5 - 10mg daily for 5 - 10 days until 2 days before anticipated onset of menstruation.

Maintenance of pregnancy
Twice weekly or more frequent (maximum: daily) injections of 25 - 100mg 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 200mg at the discretion of the physician.

As the indications for Gestone are restricted to women of child-bearing age, dosage recommendations for children and the elderly are not appropriate.

Gestone is given by intramuscular injection. It should be injected deep into the buttock, rather than the thigh or deltoid, using a 1.5 inch (3.8cm) needle. This site has ample fat cells where a depot of progesterone can be formed for slow release.

4.3 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.

4.4 Special warnings and precautions for use

Gestone 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, sudden or gradual, partial or complete loss of vision, proptosis or diplopia, papilloedema, retinal vascular lesions or migraine occur during therapy, the drug should be discontinued and appropriate diagnostic and therapeutic measures instituted.

4.5 Interactions with other medicinal products and other forms of Interaction

Gestone may interfere with the effects of bromocriptine. Gestone may affect the results of laboratory tests of hepatic and/or endocrine functions.

Gestone may raise the plasma concentration of cyclosporin.

4.6 Pregnancy and lactation
Gestone may be used to maintain pregnancy where there is deficient production of endogenous progesterone from the corpus luteum. It should not be necessary to administer Gestone once there is adequate secretion of placental progesterone. Gestone contains progesterone itself, the same as the naturally secreted hormone, and is not associated with masculinization of a female foetus as are synthetic progestins.

Detectable amounts of progesterone enter the breast milk. As the effect on the suckling infant has not been determined, the use of Gestone during lactation is not recommended.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Breakthrough bleeding, change in menstrual flow, amenorrhoea, changes in cervical erosion and secretions, breast changes, oedema, weight gain, catabolism, cholestatic jaundice, allergic reactions and rashes, acne, chloasma, mental depression, pyrexia, insomnia, somnolence, nausea, alopecia, hirsutism, local reactions at site of injection.

4.9 Overdose

This is unlikely and is not expected to produce any adverse effects. Treatment is observation and, if necessary, symptomatic and supportive measures should be provided.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Progesterone is a progestogen, the main hormone of the corpus luteum and the placenta. It acts on the endometrium by converting the proliferating phase to the secretory phase.
5.2 Pharmacokinetic properties

When given intramuscularly, the injection provides depot therapy.

5.3 Preclinical safety data

There are no preclinical data of relevance to the Prescriber which are additional to those already included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethyl oleate BP
Benzyl alcohol

6.2 Incompatibilities

None stated.

6.3 Shelf life

60 months as packaged for sale.

6.4 Special precautions for storage

Protect from light and store at room temperature (15 - 25ºC).

6.5 Nature and contents of container

Each pack contains 10x 2ml clear glass ampoules. Each ampoule contains a pale yellow oily sterile solution of Progesterone BP in ethyl oleate (100mg/2ml) with benzyl alcohol (10%).
6.6 Instructions for use/handling

None stated.

Administration Details

7 MARKETING AUTHORISATION HOLDER

Nordic Pharma Limited
Abbey House
1650 Arlington Business Park
Theale
Reading
Berkshire
RG7 4SA
United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 05827/0013

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

25th March 2003

10 DATE OF REVISION OF THE TEXT

11/01/2008