

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Gestone 50 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ampoule contains progesterone, 100 mg in 2 ml.

Excipients with known effects: This medicinal product contains 200 mg benzyl alcohol in each ampoule, equivalent to 100 mg/ml (see section 4.4).

For the full list of excipients see Section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

Clear, colourless to slightly yellow oily solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Gestone 50 mg/ml solution for injection 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

Posology

Dysfunctional uterine bleeding

5 – 10 mg 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 25-100 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.

Special Populations

The indications for Gestone 50mg/ml solution for injection are restricted to women of child-bearing age.

Elderly

Dosage recommendations for the elderly are not appropriate.

Paediatric population

Dosage recommendations for children are not appropriate.

Method of administration

For intramuscular use.

Gestone 50 mg/ml solution for injection 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 the active substance or any of the excipients listed in section 6.1.

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 (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 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.

Excipient with known effect:

Gestone 50 mg/ml Solution for Injection contains benzyl alcohol which may cause allergic reactions.

Gestone 50 mg/ml Solution for Injection contains benzyl alcohol, large amounts of benzyl alcohol can build up in the body causing metabolic acidosis. Therefore, Gestone 50 mg/ml Solution for Injection must be used with caution in patients who have liver or kidney disease and those who are breast-feeding (also refer to section 4.6 Fertility, pregnancy and lactation - Gestone 50 mg/ml Solution for Injection is not recommended for use during lactation).

4.5. Interactions with other medicinal products and other forms of interaction

Gestone 50 mg/ml Solution for Injection may interfere with the effects of bromocriptine. Gestone 50 mg/ml Solution for Injection may affect the results of laboratory tests of hepatic and/or endocrine functions.

Gestone 50 mg/ml Solution for Injection may raise the plasma concentration of cyclosporin.

4.6. Fertility, pregnancy and lactation

Gestone 50 mg/ml Solution for Injection 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 50 mg/ml Solution for Injection contains progesterone itself, the same as the naturally secreted hormone, and is not associated with masculinisation 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 50 mg/ml Solution for Injection during lactation is not recommended.

4.7. Effects on ability to drive and use machines

Gestone 50 mg/ml Solution for Injection has no or negligible influence on the ability to drive and use machines.

4.8. Undesirable effects

Post-Marketing experience

The information given below is based on post-marketing experience from the administration of progesterone.

Adverse effects have been ranked under headings of frequency using the following convention: very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$); frequency not known (cannot be estimated from the available data).

| System organ class | Frequency Not known (cannot be estimated from the available data) |
|----------------------------|--|
| Gastrointestinal disorders | Nausea |

| | |
|--|---|
| General disorders and administration site conditions | Injection site reaction, Oedema |
| Hepatobiliary disorders | Pyrexia, Cholestatic jaundice |
| Immune System Disorders | Allergic reaction |
| Investigations | Weight gain |
| Metabolism and nutrition disorders | Catabolism increased |
| Psychiatric disorders | Insomnia, Depression mental, Somnolence |
| Reproductive system and breast disorders | Amenorrhoea, Breakthrough bleeding, Menstrual flow altered, Erosion and ectropion of the cervix, Cervical discharge, Breast fibrocystic changes |
| Skin and subcutaneous tissue disorders | Acne, Alopecia, Chloasma, Hirsutism, Rash |

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the MHRA Yellow Card scheme (website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store).

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

ATC code: G03DA04

Gestone 50 mg/ml solution for injection is natural progesterone.

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
Benzyl alcohol

6.2. Incompatibilities

None applicable.

6.3. Shelf life

2 years

6.4. Special precautions for storage

Store below 25°C. Store in the original package in order to protect from light.

6.5. Nature and contents of container

A pack contains 10 x 2 ml clear glass ampoules in a cardboard carton.

6.6. Special precautions for disposal

Any unused medicinal product or waste material should be discarded in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Nordic Pharma Limited,
Building 1410, Arlington Business Park
Theale, Reading
RG7 4SA
United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 05827/0025

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

25th March 2003

10. DATE OF REVISION OF THE TEXT

14th May 2026