

PACKAGE LEAFLET: INFORMATION FOR THE USER

Gestone 50mg/ml Solution for Injection (progesterone)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

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1. What your medicine is and what it is used for

The name of your medicine is Gestone 50mg/ml Solution for Injection. The active ingredient of Gestone 50mg/ml Solution for Injection is Progesterone (a hormone which acts on the lining of the uterus and is produced naturally by the body). Each 2 ml ampoule of Gestone 50 mg/ml Solution for Injection contains 100 mg of Progesterone in 2 ml of liquid. This medicine contains 100 mg of benzyl alcohol in 1ml of liquid which is equivalent to 100 mg/ml.

It may be prescribed in women for the following conditions:-

- To help early pregnancy to continue in cases where the body is not producing enough progesterone and where there have been 3 or more unexplained miscarriages
- In selected cases, to assist infertility treatment techniques such as in-vitro fertilisation (IVF) or gamete intra-fallopian transfer (GIFT)
- Bleeding disorders of the uterus.

2. What you need to know before you use this medicine

Do not use Gestone 50mg/ml Solution for Injection if:

- you are allergic to progestins, or any of the ingredients of this medicine
- you are suffering from vaginal bleeding other than during periods
- you have ever had a missed or incomplete abortion
- you have, or have ever had, breast cancer or cancer of the reproductive tract
- you have redness, swelling or pain of the veins or any other related problem
- you have ever had a stroke, or bleeding in the brain

- you have liver disease.

Tell your doctor if any of the above conditions apply to you, before you use Gestone 50 mg/ml Solution for Injection.

Warnings and precautions

Talk to your doctor or pharmacist before using this medicine if:

- you have high blood pressure, heart disease or kidney disease
- you have epilepsy
- you suffer, or have ever suffered, from mental depression
- you are diabetic
- you suffer from porphyria
- you are breast feeding a child
- you have a sensitivity to light
- you suffer from migraine attacks
- you are having regular blood tests to check your liver or hormones (Gestone 50 mg/ml Solution for Injection may interfere with these tests).

Children

Gestone 50 mg/ml Solution for Injection is not for use in children.

Other medicines and Gestone 50 mg/ml Solution for Injection

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Before using Gestone 50mg/ml Solution for Injection please check with your doctor if you are taking any of the following:-

- bromocryptine
- ciclosporin

Pregnancy, breast-feeding and fertility

Gestone 50mg/ml Solution for Injection will support pregnancy if you are having fertility treatment. See Section 3 on how to use Gestone 50mg/ml Solution for Injection.

Use of Gestone 50mg/ml Solution for Injection is not recommended if you are breast-feeding.

Driving and using machines

It is not known whether Gestone 50mg/ml Solution for Injection affects your ability to drive or operate machinery. Do not drive or operate machinery if you feel sleepy after using Gestone 50mg/ml Solution for Injection.

Excipients warnings

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

Ask your doctor or pharmacist for advice before you use Gestone 50mg/ml Solution for Injection if you are breast-feeding, or if you have liver or kidney disease. This is because large amounts of benzyl alcohol can build up in your body and may cause side effects (called metabolic acidosis).

3. How to use your medicine

Your doctor or nurse will advise you on how Gestone 50mg/ml Solution for Injection should be given at home. Gestone 50mg/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.

The number of injections given to you per day or per week is called the 'dose'. Depending on which condition you are being treated for, the appropriate dose is given by injection into a muscle (this should be deep into the buttock rather than the thigh) using a 1.5 inch (3.8 cm) needle. The site of injection has ample fat cells where a depot of progesterone can be formed for slow release.

The dose varies depending on the reason you are prescribed progesterone. Suggested doses and durations of doses are detailed below, but these may vary in your particular case according to advice from your specialised prescriber. If you are not sure ask your prescriber.

The most common dose for bleeding of the uterus is 5-10 mg daily for 5-10 days until 2 days before the anticipated start of a menstrual period.

The most common dose for maintaining pregnancy is twice weekly (or more frequent) injections of 25-100 mg starting from about 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. The maximum frequency of injections should be once a day.

Daily dosage can be increased to 200 mg at the discretion of your doctor.

Use in children

The use of Gestone 50mg/ml Solution for Injection is only for women of child bearing age. There are no appropriate dosage recommendations for children or the elderly.

If you forget to take or use more Gestone 50 mg/ml Solution for Injection than you should

If you think that you have missed a dose or have been given too much Gestone 50 mg/ml Solution for Injection, please tell a nurse or doctor.

4. Possible side effects

Like all medicines, Gestone 50 mg/ml Solution for Injection can cause side effects, although not everybody gets them.

If any of the following side effects occur suddenly, or gradually, without explanation, contact the doctor or your nearest hospital casualty department at once:

- problems with vision (such as blurred vision, partial vision, sudden short-sightedness or complete loss of vision)
- any swelling of the eye

- migraine type headache.

The following side effects may occur with this medicine:

Frequency not known (frequency cannot be estimated from the available data):

- Breakthrough bleeding, changes in period flow, missed periods, changes in vaginal secretions
- breast changes
- fluid retention with swelling
- weight gain
- weight loss
- jaundice (yellowing of the skin or eyes)
- allergic reactions (skin rash, or sudden pain, swelling, shortness of breath or fever)
- acne
- dark colouration of the skin on the face
- mental depression
- fever
- sleep disturbance (difficulty with sleeping at night, or falling asleep during the day)
- nausea
- hair loss from the scalp
- excessive hair growth on the face or body
- local irritation (reactions) at the site of injection.

Reporting of side effects

If you get any side effects, talk to your dentist, doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the UK Yellow Card Scheme (website: www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store your medicine

Keep out of the reach and sight of children.

Store your medicine in the original package to protect it from light. Store at or below 25°C. During storage, solid matter may form in the ampoule. This should be re-dissolved by warming the ampoule before use.

On the label you will find the letters “EXP” followed by some numbers. These numbers are the date when the medicine is no longer fit for use. Do not use this medicine after this date.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines which you no longer require. These measures will help to protect the environment.

6. Contents of the pack and other information

What Gestone 50mg/ml Solution for Injection ampoules contain

Each 2 ml ampoule of Gestone 50mg/ml Solution for Injection contains 100 mg of Progesterone in 2 ml of liquid.

The ampoules also contain benzyl alcohol and ethyl oleate.

What Gestone 50mg/ml Solution for Injection ampoules look like and contents of the pack

Gestone 50 mg/ml Solution for Injection is a sterile, pale yellow oily liquid. It is supplied in clear glass ampoules in packs containing 10 ampoules.

Marketing Authorisation Holder

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

Manufacturer

Qmed Pharmaceuticals Ltd, Unit 4, Thornham Grove, London, E15 1DN, UK

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