PRODUCT INFORMATION

PRIMOTESTON® DEPOT

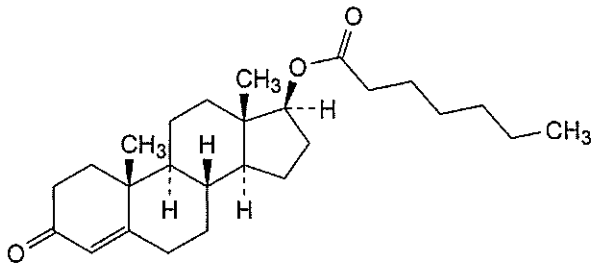
(testosterone enanthate)

NAME OF THE MEDICINE

Testosterone enanthate is designated chemically as 17 beta-heptanoyloxy-4-androstene-3-one.

The empirical formula of testosterone enanthate is $C_{26}H_{40}O_3$ and its molecular weight is 400.66 g/mol. Its chemical structure is shown in Figure 1.
(CAS number: 315-37-7)

Figure 1.



DESCRIPTION

1 mL Primoteston Depot contains 250 mg testosterone enanthate (equivalent to approximately 180 mg testosterone) in clear, yellowish oily solution for injection.

Primoteston Depot contains the following excipients: benzyl benzoate and castor oil.

PHARMACOLOGY

The depot effect of testosterone enanthate permits long intervals between injections. This ester not only has a long-lasting, but also a very intensive androgenic effect. The duration of action of 1 mL Primoteston Depot is approximately 2-4 weeks depending on the initial hormonal status.

INDICATIONS

Androgen replacement therapy for confirmed testosterone deficiency in males.

CONTRAINDICATIONS

Prostatic carcinoma, mammary carcinoma in males.

Hypercalcaemia accompanying malignant tumours.

Previous or existing liver tumours.

Hypersensitivity to any of the ingredients.

PRECAUTIONS

The general aim of androgen replacement therapy for confirmed testosterone deficiency in males is to keep serum testosterone levels within the reference range for the age group concerned. Over-replacement should be avoided.

Androgens are not indicated for enhancing muscular development in healthy individuals or for increasing physical ability.

Older patients treated with androgens may be at increased risk for the development of prostatic hyperplasia. Androgens can enhance the growth of an existing prostatic carcinoma. Therefore, carcinoma of the prostate has to be excluded before starting therapy with testosterone preparations.

As a precaution, regular examinations of the prostate are recommended. Haemoglobin and haematocrit should be checked periodically in patients on long-term androgen therapy to detect cases of polycythaemia (see ADVERSE EFFECTS).

Cases of benign and malignant liver tumours, which may lead to life-threatening intra-abdominal haemorrhage, have been observed after the use of hormonal substances such as the one contained in Primoteston Depot. The doctor must therefore be informed of the occurrence of unusual upper abdominal complaints which do not disappear spontaneously within a short time as it may then be necessary to withdraw the preparation. A hepatic tumour should be considered in the differential diagnosis when severe upper abdominal pain, liver enlargement or signs of intra-abdominal haemorrhage occur in men using Primoteston Depot.

Caution should be exercised in patients predisposed to oedema, as treatment with androgens may result in increased sodium retention.

Primoteston Depot must not be used in women, due to possible virilising effects.

Pre-existing sleep apnoea may be potentiated.

As with all oily solutions, Primoteston Depot must be injected intramuscularly and extremely slowly. Pulmonary microembolism of oily solutions can lead to signs and symptoms such as cough, dyspnoea and chest pain. There may be other signs and symptoms including vasovagal reactions such as malaise, hyperhydrosis, dizziness, paraesthesia, or syncope. These reactions may occur during or immediately after the injection and are reversible. Treatment is usually supportive, e.g. by administration of oxygen.

Use in Pregnancy

Primoteston Depot is intended for use in men only. Primoteston is not indicated for use in pregnant women.

Use in Lactation

Primoteston Depot is intended for use in men only. Primoteston is not indicated for use in breast feeding women.

Paediatric Use

Primoteston Depot is not indicated for use in children and adolescents.

In addition to causing masculisation in children, testosterone can cause accelerated growth and bone maturation and premature epiphyseal closure, thereby reducing adult height.

Use in the Elderly

Limited data do not suggest the need for a dosage adjustment in elderly patients.

Use in Patients with Impaired Hepatic Function

No formal studies have been performed in patients with liver impairment. The use of Primoteston Depot is contraindicated in men with past or present liver tumours.

Use in Patients with Impaired Renal Function

No formal studies have been performed in patients with renal impairment.

INTERACTIONS WITH OTHER MEDICINES

Phenobarbital increases the break-down of steroid hormones in the liver (possible impairment of efficacy).

The clotting status should be monitored particularly closely when Primoteston Depot is administered together with coumarin derivatives.

ADVERSE EFFECTS

The most commonly reported adverse reactions with Primoteston Depot are injection site pain, injection site erythema, and cough and/or dyspnoea during or immediately after the injection.

Injections of oily solutions such as Primoteston Depot have been associated with systemic reactions: cough, dyspnoea and chest pain. There may be other signs and symptoms including vasovagal reactions such as malaise, hyperhydrosis, dizziness, paraesthesia or syncope.

High-dosed or long-term administration of testosterone, including Primoteston Depot, increases the tendency to water retention and oedema.

Spermatogenesis is inhibited by long-term and high-dosed treatment with Primoteston Depot.

If, in individual cases, frequent or persistent erections occur, the dose should be reduced or the treatment discontinued in order to avoid injury to the penis.

Various skin reactions including injection site reactions (injection site pain, injection site erythema, injection site induration, injection site swelling, injection site inflammation) may occur.

Other events reported with Primoteston Depot include benign and malignant liver tumours, polycythaemia, hypersensitivity reactions, liver function test abnormalities, jaundice, acne, alopecia, rash, urticaria, pruritus, Prostatic Specific Antigen (PSA) increase, libido increase, libido decrease and gynaecomastia.

Regarding adverse effects associated with the use of androgens, please also refer to PRECAUTIONS.

DOSAGE AND ADMINISTRATION

Like all oily solutions, Primoteston Depot must be injected intramuscularly, immediately after drawing up into the syringe, and extremely slowly (see PRECAUTIONS).

For the development and stimulation of still underdeveloped androgen-dependent target organs and for the initial treatment of deficiency symptoms: 1 prefilled syringe i.m. every 2-3 weeks.

To maintain an adequate androgenic effect, 1 prefilled syringe i.m. every 3-4 weeks. Shorter injection intervals may be necessary depending on the individual requirement for hormone, but longer intervals of up to 6 weeks are also sufficient in many cases.

Serum testosterone levels should be measured before start of treatment and periodically during the treatment as recommended by current treatment guidelines.

OVERDOSAGE

No special therapeutic measure apart from termination of therapy with the drug or dose reduction is necessary after overdosage.

Acute toxicity data show that testosterone enanthate, the ester contained in Primoteston Depot, is to be classified as non-toxic following single intake. Even following single administration of a multiple of the dose required for therapy, no toxicity risk is to be expected.

PRESENTATION AND STORAGE CONDITIONS

1 mL prefilled syringes containing 250 mg testosterone enanthate.

Primoteston Depot should be stored below 25 °C. Keep out of reach of children. Protect from light.

NAME AND ADDRESS OF THE SPONSOR

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POISON SCHEDULE OF THE MEDICINE

PRESCRIPTION ONLY MEDICINE

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (THE ARTG)

19 August 1991

DATE OF MOST RECENT AMENDMENT

13 December 2012

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