LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Testosteronenantat SIT
(testosterone enantate)

SE/H/2435/01/DC

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testosterone enantate

solution for injection, 250 mg/mL

This is a summary of the public assessment report (PAR) for Testosteronenantat SIT. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Testosteronenantat SIT and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Testoviron-Depot.

The product contains testosterone enantate, a synthetic version of the naturally occurring male sex hormone testosterone.

It is used in adult men for testosterone replacement to treat various health problems caused by a lack of testosterone (male hypogonadism). This should be confirmed by two separate blood testosterone measurements and also include clinical symptoms, such as:
- Impotence
- Infertility
- Low sex drive
- Tiredness
- Depressive moods
- Bone loss caused by low hormone levels.

How does Testosteronenantat SIT work?

The drug is a synthetic androgen (male sex hormone) of the anabolic steroid kind and hence it is an activator of the androgen receptor, the biological target of androgens like testosterone and dihydrotestosterone.

It has strong androgenic effects and moderate anabolic effects, which make it useful for producing masculinization and suitable for androgen replacement therapy.

Testosterone enanthate is a long-lasting prodrug of testosterone in the body. Because of this, it is considered to be a natural and bioidentical form of testosterone, ready to be activated into a drug.

How is Testosteronenantat SIT used?

The pharmaceutical form is solution for injection. The product should be injected deeply into the gluteal muscle (the buttock area), where it can be stored and gradually released from into the blood circulation.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Testosteronenantat SIT have been shown in studies?

No additional studies were needed as the product is a generic medicine that is given by intravenous injection and contains the same active substance as the reference medicine Testoviron-Depot.

What are the possible side effects from Testosteronenantat SIT?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Testosteronenantat SIT approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered similar to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Testoviron-Depot, the benefits are greater than its risks and recommended that it can be approved for use.

The product has been authorised with the condition to perform further studies and/or to provide additional measures to minimise the risk. See section below “What measures are being taken to ensure the safe and effective use of Testosteronenantat SIT?”

What measures are being taken to ensure the safe and effective use of Testosteronenantat SIT?

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Specific Follow-up questionnaires (FUQs) for “Suspected Pulmonary Oil Microembolism” and “Thromboembolic risk secondary to haematocrit increase” have been updated as requested.

An Educational Brochure (Administration Guide) including the corresponding key messages has been included in the submitted RMP V0.4, signed 15 May 2024, as requested.

Other information about Testosteronenantat SIT

The full PAR for Testosteronenantat SIT can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Testosteronenantat SIT, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2024-12.