LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Testosterone Teva
(testosterone undecanoate)

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Summary Public Assessment Report

Testosterone Teva
testosterone, testosterone undecanoate

Solution for injection, 1000 mg/4 ml

This is a summary of the public assessment report (PAR) for Testosterone Teva. 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 Testosterone Teva 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 NEBIDO.

Testosterone Teva contains testosterone, a male hormone, as the active ingredient. Testosterone Teva is injected into a muscle in your body. There it can be stored and gradually released over a period of time. Testosterone Teva is used in adult men for testosterone replacement to treat various health problems caused by a lack of testosterone (male hypogonadism). These 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 Testosterone Teva work?

Testosterone undecanoate is an ester of the naturally occurring androgen, testosterone. The active form, testosterone, is formed by cleavage of the side chain.

Testosterone is the most important androgen of the male, mainly synthesized in the testicles, and to a small extent in the adrenal cortex.

Testosterone is responsible for the expression of masculine characteristics during foetal, early childhood, and pubertal development and thereafter for maintaining the masculine phenotype and androgen-dependent functions (e.g. spermatogenesis, accessory sexual glands). It also performs functions, e.g. in the skin, muscles, skeleton, kidney, liver, bone marrow, and CNS.

Dependent on the target organ, the spectrum of activities of testosterone is mainly androgenic (e.g. prostate, seminal vesicles, epididymis) or protein-anabolic (muscle, bone, haematopoiesis, kidney, liver).

The effects of testosterone in some organs arise after peripheral conversion of testosterone to oestradiol, which then binds to estrogen receptors in the target cell nucleus e.g. the pituitary, fat, brain, bone, and testicular Leydig cells.

How is Testosterone Teva used?

The pharmaceutical form is solution for intramuscular injection.

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 Testosterone Teva have been shown in studies?

No additional studies were needed as the product is a generic medicine that is given by intramuscular injection and contains the same active substance as the reference medicine, NEBIDO.

What are the possible side effects from Testosterone Teva?
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 Testosterone Teva approved?

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

What measures are being taken to ensure the safe and effective use of Testosterone Teva?

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.

The MAH has submitted a risk management plan, in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to Testosterone Teva.

Safety specification
The MAH has submitted the version 1.1 RMP dated May 31, 2022, and proposed the following summary safety concerns:

List of important risks and missing information	
Important identified risks	• Pulmonary oil microembolism (POME)
Important potential risks	• Thromboembolic risk secondary to haematocrit increase
Missing information	• None

Other information about Testosterone Teva

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

This summary was last updated in 2023-01.