

Summary Public Assessment Report

Testosterone Besins (testosterone undecanoate, testosterone)

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testosterone undecanoate, testosterone

Solution for injection, 1000 mg/4 ml

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

The product is used in adult men for testosterone replacement to treat various health problems caused by a lack of testosterone (male hypogonadism).

How does Testosterone Besins work?

Testosterone Besins contains testosterone, a male hormone, as the active ingredient.

Testosterone Besins is injected into a muscle in your body. There it can be stored and gradually released over a period of time.

How is Testosterone Besins used?

The pharmaceutical form is solution for 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 Besins have been shown in studies?

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

What are the possible side effects from Testosterone Besins?

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 Besins approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be therapeutically equivalent 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 Besins?

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.

Other information about Testosterone Besins

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

This summary was last updated in 2023-11.