# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Nebido 1000 mg/4 ml, solution for injection

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml solution for injection contains 250 mg testosterone undecanoate corresponding to 157.9 mg testosterone.

Each ampoule / vial with 4 ml solution for injection contains 1000 mg testosterone undecanoate corresponding to 631.5 mg testosterone.

Excipient with known effect:
2000 mg benzyl benzoate per ampoule / vial.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Solution for injection

*Product imported from Spain:*
Clear, colorless to yellowish-brown oily solution

## 4 CLINICAL PARTICULARS

As per PA2242/015/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA2242/015/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Benzyl Benzoate
Castor Oil, Refined

### 6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

### 6.3 Shelf life

The shelf life expiry date of this product is the date shown on the vial and outer carton of the product as marketed in the country of origin.

The medicinal product must be used immediately after first opening.

### 6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

**6.5 Nature and contents of container**

Vial:
1 brown glass vial with 4 ml of solution for injection
Pack size: 1 x 4 ml.

**6.6 Special precautions for disposal and other handling**

At cold storage temperatures the properties of this oil-based solution might temporarily change (e.g. higher viscosity, cloudiness). If stored at cold temperature, the product should be brought to room or body temperature before use.

The solution for intramuscular injection is to be visually inspected prior to use and only clear solutions free from particles should be used.

The medicinal product is for single use only and any unused solution should be discarded in accordance with local requirements.

Vial

The vial is for single use only. The content of a vial is to be injected intramuscularly immediately after drawing up into the syringe. After removal of the plastic cap (A) do not remove the metal ring (B) or the crimp cap (C).


**7 PARALLEL PRODUCT AUTHORISATION HOLDER**

IMED Healthcare Ltd.
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**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/256/001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 9th January 2026

**10 DATE OF REVISION OF THE TEXT**