

Administration guide for Nebido (testosterone undecanoate) 1000 mg/4 ml solution for injection

Important safety information for healthcare professionals

This educational material provides information on certain aspects of Nebido administration in order to widen your knowledge on events that might occur during or after the injection.

The guide should be read in conjunction with the Summary of Product Characteristics, available on www.medicines.ie and www.hpra.ie.

Nebido – the long-acting testosterone

Check for contraindications and special warnings according to the Summary of Product Characteristics

Before administering the injection, check the patient for any contraindications: androgen-dependent carcinoma of the prostate or of the male mammary gland; past or present liver tumours; hypersensitivity to the active substance or to any of the excipients.¹ Nebido is not indicated for use in women.¹

Preparing the injection

There is no specific storage conditions associated with the product.

If refrigerated, allow to reach room temperature before injection.

Gloves should be worn while removing the plastic cap on the vial.

Do not remove the metal ring or the crimp cap.¹

Sterilise the rubber membrane

Use an alcohol wipe to sterilise the rubber membrane, which is now exposed, before withdrawing the medication.

The glass vial is for single use only. The content of a vial is to be injected intramuscularly immediately.

Use a 5ml syringe

Needle Sizes

- Withdraw the solution by positioning the needle at the lowest point in the vial, using an 18G (1.2mm) x 50mm needle.
- Use a 5ml syringe and withdraw 4ml solution from the glass vial.
- Select the appropriate needle size according to the patient's fat and muscle mass of the gluteal region.
- Experts recommend the use of a 20G (0.9mm), 21G^{2,3} (0.8mm) or 22G (0.7mm) needle to ensure a slow intramuscular injection and deposition of Nebido.

Preparation of patient

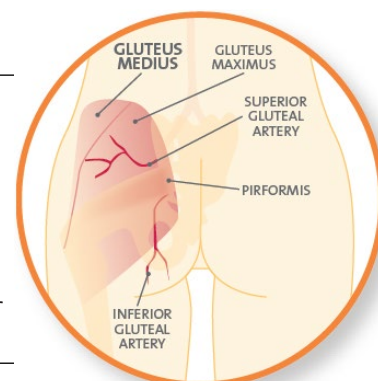
Lay the patient down in a comfortable position

- The deep, intramuscular injection should be administered with the patient lying down.
- The bed should be completely flat and the patient's hands should be kept under their head.
- You should also remind the patient to remain still during the injection.

Performing the injection

The preferred site for intramuscular injection is the gluteus medius muscle located in the upper outer quadrant of the buttock.

Care must be taken to prevent the needle from hitting the superior gluteal artery and sciatic nerve. The solution should not be split into portions and it should never be administered into the upper arm or thigh.



Administration guide for Nebido (testosterone undecanoate)

The injection process – step-by-step

- As with all oil-based solutions, Nebido must be injected strictly intramuscularly and very slowly.¹
- It is recommended to inject the solution over approximately 2 minutes.¹
- After selecting the injection site, cleanse the area with an antiseptic.
- If there is little muscle mass, you may need to pinch up 2 to 3 edges of the gluteal muscle to provide more volume and tissue to insert the needle.
- Insert the needle into the skin at a 90° angle to ensure it is deeply embedded in the muscle.
- Grasp the barrel of the syringe firmly with one hand. Using the other hand, pull the plunger back to aspirate for blood:
 - If blood appears, do not proceed with the injection. Take the needle out of the patient immediately and replace it,
 - Carefully repeat the steps for injection.
- If no blood is aspirated, hold the needle position to avoid any movement.
- Apply the injection very slowly by depressing the plunger carefully and at a constant rate until all the medication is delivered (ideally over 2 minutes).
- If possible, use your free hand to manually probe or check for depot formation.
- Withdraw the needle.

The patient should be observed during and immediately after each injection in order to allow for early recognition of possible signs and symptoms that may indicate pulmonary oil microembolism (POME).¹

Risk management of Nebido-treated patients

The preparation

Nebido is an oil-based solution that contains 1000mg testosterone undecanoate (TU) dissolved in 4ml castor oil.¹

As with all oil-based solutions, it must be injected strictly intramuscularly and very slowly.¹

Intramuscular injection of an oil-based preparation requires special care to prevent accidental, direct delivery of the oil-based solution to the vascular system.

Pulmonary oil microembolism (POME)

POME is an injection-based reaction and is pathophysiologically related to fat embolism syndrome. It can occur following direct vascular or lymphovascular delivery of oil-based preparations, which then reach the lung from venous circulation and right heart output.

Pulmonary oil microembolism can in rare cases lead to signs and symptoms such as: cough (or urge to cough), dyspnoea, malaise, hyperhidrosis, chest pain, dizziness, paraesthesia, or syncope.¹

These reactions may occur during or immediately after the injection and are reversible. Treatment is usually supportive, e.g. by administration of supplemental oxygen.¹

Sometimes these symptoms may be difficult to distinguish from an allergic reaction that can occur with use of any injectable product.

Suspected anaphylactic reactions after the injection have been reported.¹

References: 1. Nebido Summary of Product Characteristics. 2. Sartorius *Get al.* Asian J Androl 2010;12(2):227–233. 3. Middleton *Tet al.* Eur J Endocrinol 2015;172(5):511–517

Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, website: www.hpra.ie.

Adverse events should also be reported to Grünenthal Pharma Ltd: drugsafety.IE@grunenthal.com.

For medical information enquiries or to request a hard copy of this guide, please email: IEmedicalinformation@grunenthal.com.

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