



Administration guide for Nebido[®](testosterone undecanoate) Information for healthcare professionals

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

Please refer to the full Summary of Product Characteristics .

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

Nebido® – preparing the injection



**Do not inject
refrigerated
solution**

Use a 5ml syringe

Needle sizes

- Withdraw the solution by positioning the needle at the lowest point in the vial [or ampoule], using an 18G (1.2mm) x 50mm needle
- Use a 5ml syringe and withdraw 4ml Nebido® solution from the glass vial [or ampoule]
- 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. Nebido® should not be split into portions and it should never be administered into the upper arm or the thigh

The injection process – step-by-step

- As with all oil-based solutions, Nebido® must be injected strictly intramuscularly and very slowly¹
- It is recommended to inject Nebido® over approximately 2 minutes¹
- After selecting the injection site, cleanse the area with antiseptic
- If there is little muscle mass, you may need to pinch up two to three 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 probe manually or check for depot formation
- Withdraw the needle

The patient should be observed during and immediately after each injection of Nebido® 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

Nebido® – the preparation

Nebido® is an oil-based solution that contains 1000mg TU dissolved in 4ml castor oil.¹

As with all oil-based solutions, Nebido® 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 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 Nebido® injection have been reported.¹

Healthcare Professionals are asked to report any suspected adverse reactions

Suspected adverse reactions and medication errors should be reported. Report forms can be downloaded from:

www.medicinesauthority.gov.mt/adrportal

and sent to:

E: postlicensing.medicinesauthority@gov.mt

Or

E: pv@alfredgera.com

References

1. Nebido Summary of Product Characteristics. January 2017
2. Sartorius G et al. *Asian J Androl* 2010;12(2):227-233
3. Middleton T et al. *Eur J Endocrinol* 2015;172(5):511-517

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