

## Important Safety Information

Guidance on the administration of Testosterone Undecanoate EVER Pharma

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

See the full Summary of Product Characteristics for further information.

For further information please contact EJ Busuttil Ltd via email to [safety@ejbusuttil.com](mailto:safety@ejbusuttil.com) or by phoning on 00356 21447184.

### What is Testosterone Undecanoate ?

Testosterone Undecanoate (TU) is a long-acting testosterone preparation for the treatment of male hypogonadism confirmed by clinical symptoms and biochemical tests. The intramuscular injection forms a depot from which TU is gradually released.<sup>1</sup> The objective of this educational booklet is to:

- Provide guidance to healthcare professionals on the administration and handling of Testosterone Undecanoate.
- Increase awareness and knowledge of possible adverse events, namely pulmonary oil microembolism (POME)

### 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.

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

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

POME can in rare cases lead to signs and symptoms such as:<sup>1</sup>

- |                            |                |
|----------------------------|----------------|
| ▪ Cough (or urge to cough) | ▪ Chest pain   |
| ▪ Dyspnea                  | ▪ Dizziness    |
| ▪ Malaise                  | ▪ Paraesthesia |
| ▪ Hyperhidrosis            | ▪ Syncope      |

## **Suspected anaphylactic reactions**

Suspected anaphylactic reactions after Testosterone Undecanoate injection have been reported.<sup>1</sup> Please follow local guidelines for the management of a suspected anaphylactic reaction.<sup>1</sup> The patient should be observed during and immediately after each injection of Testosterone Undecanoate in order to allow for early recognition of possible signs and symptoms that may indicate pulmonary oil microembolism (POME) and suspected anaphylactic reactions.<sup>1</sup>

## **For full information on contraindications and special warnings please refer 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.<sup>1</sup> Testosterone Undecanoate is not indicated for use in women.<sup>1</sup>

## **How to prepare the intramuscular injection**

Do not inject refrigerated solution. Bring solution to ambient room temperature before injecting it.

## **Use a 5ml syringe**

### Needle sizes

- Withdraw the solution by positioning the needle at the lowest point in the vial, using an 18G blunt drawing up (1.2mm) x 50 mm needle
- Use a 5ml syringe and withdraw 4ml Testosterone Undecanoate solution from the glass vial
- Select the appropriate needle size according to the patient's fat and muscle mass of the gluteal region
- The use of 20G (0,9 mm), 21G2,3 (0,8 mm) or 22G (0,7 mm) needle ensures a slow intramuscular injection and deposition of Testosterone Undecanoate

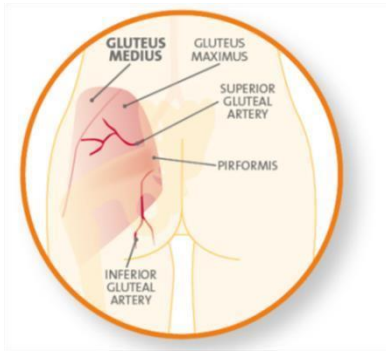
## **Optimal patient positioning**

### 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

## **Where to administer the intramuscular 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.
- Testosterone Undecanoate should not be split into portions and it should never be administered into the upper arm or the thigh.



### The intramuscular injection process – step-by-step

- As with all oil-based solutions, Testosterone Undecanoate must be injected strictly intramuscularly and very slowly.<sup>1</sup>
- It is recommended to inject Testosterone Undecanoate over approximately 2 minutes.<sup>1</sup>
- 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 probe manually or check for depot formation.
- Withdraw the needle.

The patient should be observed during and immediately after each injection of Testosterone Undecanoate in order to allow for early recognition of possible signs and symptoms that may indicate pulmonary oil microembolism (POME) or suspected anaphylactic reactions.<sup>1</sup>

Please report suspected adverse drug reactions (ADRs) to  
Malta Medicine Authority via the ADR Reporting Website:

[www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)

Address: Sir Temi Zammit Buildings,  
Malta Life Sciences Park,  
San Gwann SGN 3000, Malta

Alternatively, you can report a suspected side effect to EJ Busuttil Ltd  
by calling 2147184. This service is available 24/7.

When reporting please provide as much information as possible.

By reporting side effects, you can help provide more information on  
the safety of this medicine.

Adverse events should also be reported to [safety@ejbusuttil.com](mailto:safety@ejbusuttil.com)

Adverse events should also be reported to EVER Valinject (Marketing Authorisation Holder)  
at: [drugsafety@everpharma.com](mailto:drugsafety@everpharma.com) or free telephone: +43 7665 20555.

For further information about Testosteron EVER Pharma, please contact:  
EVER Valinject GmbH  
Oberburgau 3  
4866 Unterach am Attersee, Austria

For any medical information requests, please contact: [office@everpharma.com](mailto:office@everpharma.com).

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Approved by Malta Medicine Authority – Jan 25

#### References

1. Testosteron EVER Pharma Summary of Product Characteristics
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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