Important safety information for healthcare professionals

Guidance on the administration of Roxadin (testosterone undecanoate) 1000 mg/4 ml solution for injection

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

The full summary of product characteristics is available on www.medicines.org.uk

Contents

What is Roxadin?

Roxadin (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.[1]

The objective of this educational material is to:

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

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.[1] Roxadin is not indicated for use in women.[1]

How to prepare the intramuscular injection

Do not inject refrigerated solution.

Bring solution to room or body temperature before injecting it.

Use a 5 ml syringe

Needle sizes

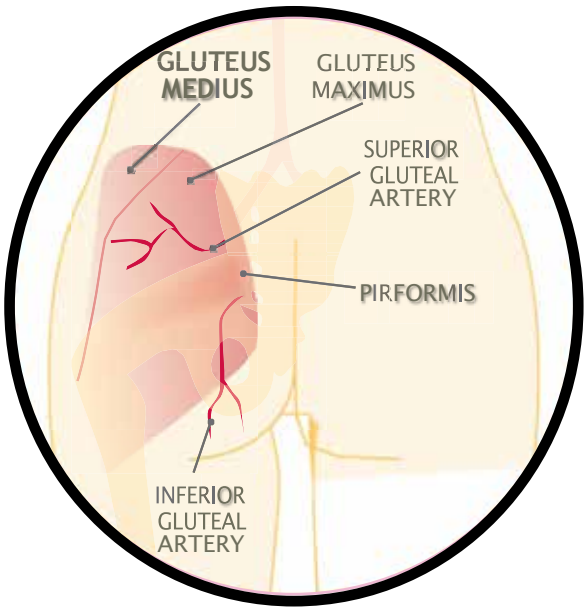
- Withdraw the solution by positioning the needle at the lowest point in the vial, using an 18G blunt drawing up (1.2mm) x 50 mm needle.
- Use a 5ml syringe and withdraw 4ml solution from the glass vial.
- Select the appropriate needle size according to the patient's fat and muscle mass of the gluteal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

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.
- The solution 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, Roxadin 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 probe manually 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) and suspected anaphylactic reactions'.[1]

Risk management of Roxadin-treated patients

The preparation

Roxadin is an oil-based solution that contains 1000mg 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.

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.

POME can in rare cases lead to signs and symptoms such as:[1]

- Cough (or urge to cough)
- Dyspnoea
- Malaise
- Hyperhidrosis
- Chest pain
- Dizziness
- Paraesthesia
- Syncope.

Suspected anaphylactic reactions

Suspected anaphylactic reactions after the injection have been reported.[1]

Please follow local guidelines for the management of a suspected anaphylactic reaction.

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) and suspected anaphylactic reactions'.[1]

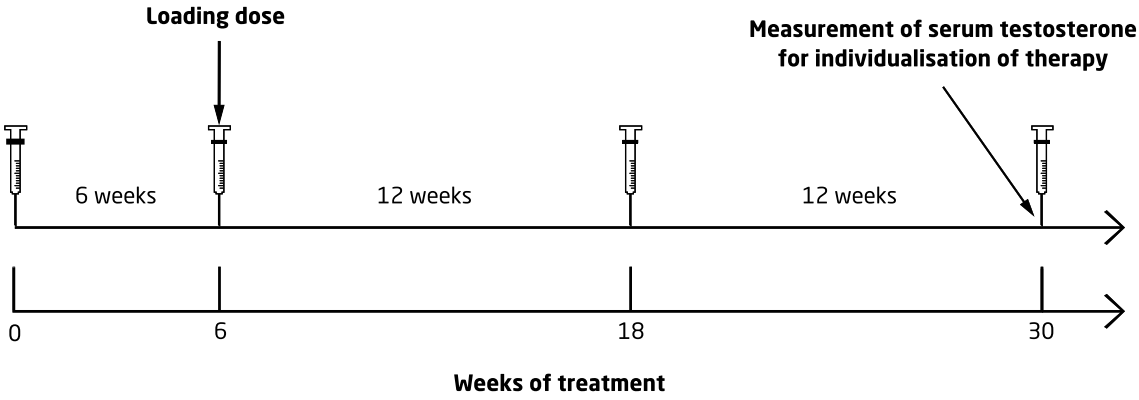
Recommended treatment schedule and follow-up

Roxadin is injected in intervals of 10–14 weeks.[1]

Starting treatment

Serum testosterone levels should be measured before start and during initiation of treatment. Depending on serum testosterone levels and clinical symptoms, the first injection interval may be reduced to a minimum of 6 weeks as compared to the recommended range of 10 to 14 weeks for maintenance. With this loading dose, sufficient steady state testosterone levels may be achieved more rapidly.[1]

Maintenance and individualisation of treatment



Careful monitoring of serum testosterone levels is required during maintenance of treatment. It is advisable to measure testosterone serum levels regularly.

Measurements should be performed at the end of an injection interval and clinical symptoms considered for individualisation of the therapy. These serum levels should be within the lower third of the normal range.

Serum levels below normal range would indicate the need for a shorter injection interval. In case of high serum levels an extension of the injection interval may be considered.

Additional follow-up

Periodic check-ups during long-term androgen therapy are recommended for prostate disease, haemoglobin, haematocrit and liver function tests and lipid profile.[1]

Adverse event reporting

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. You can report via:

- the Yellow Card website www.mhra.gov.uk/yellowcard
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals.

Alternatively, you can report a suspected adverse drug reactions to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.
When reporting please provide as much information as possible. By reporting adverse drug reactions, you can help provide more information on the safety of this medicine.

Adverse events should also be reported to **pv@galvanypharma.com**.

For further information about this medicine, please contact: Galvany Pharma, Business and Technology Centre, Bessemer Drive, Stevenage SG1 2DX, United Kingdom

To request a copy of this guide, please email: pv@galvanypharma.com.

This educational material fulfils the conditions of the marketing authorisation.

Approved by the MHRA on 10th June 2025

References
1. Roxadin 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