Testosterone

Endocrinology Shared Care Guideline

Introduction

Testosterone may be used as replacement therapy in hypogonadal adults and in those who are hypogonadal due to pituitary or testicular disease. The aim of therapy is to raise testosterone level to middle of normal range.

Licensed indications: Androgen deficiency (hypogonadism).

Unlicensed indications: Induction of puberty in delayed pubertal adolescents, management of gender identity disorders.

Injectable or topical preparations are preferred as oral testosterone undergoes extensive first pass metabolism making it difficult to maintain normal serum testosterone concentrations. Intramuscular testosterone in an oil-based vehicle allows for the gradual release of testosterone and maintenance of normal levels. Topical preparations have similar benefits resulting in relatively stable levels.

Adult Dosage and Administration

<table>
<thead>
<tr>
<th>Generic Presentation</th>
<th>Brand Name</th>
<th>Route</th>
<th>Typical Dose Regimen for Hypogonadism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Testosterone enantate inj 250mg/ml</td>
<td></td>
<td>Slow i.m</td>
<td>• Initially 250mg every 2-3 weeks. Maintenance 250mg every 3-6 weeks.</td>
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<td></td>
<td></td>
<td></td>
<td>• (Gender identity: 50mg monthly).</td>
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<tr>
<td>Testosterone undecanoate inj 1000mg/4ml</td>
<td>Nebido</td>
<td>Deep i.m</td>
<td>• 1g every 10-14 weeks</td>
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<tr>
<td>Testosterone esters inj 250mg/ml</td>
<td>Sustanon</td>
<td>Deep i.m</td>
<td>• 250mg every 3 weeks</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• (Induction of puberty: 0.6mls monthly)</td>
</tr>
<tr>
<td>Testosterone gel 50mg/5g tube</td>
<td>Testim / Testogel</td>
<td>Topical</td>
<td>• 50-100mg applied once daily</td>
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<tr>
<td>Testosterone gel 2%</td>
<td>Tostran</td>
<td>Topical</td>
<td>• Initially 60mg once daily. Max 80mg daily</td>
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<tr>
<td>(10mg/ application)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Testosterone undecanoate 40mg caps</td>
<td>Restandol Testocaps</td>
<td>Oral</td>
<td>• 120-160mg daily for 2-3 weeks. Maintenance 40-120mg daily</td>
</tr>
</tbody>
</table>

Hospital Specialist Responsibilities

- Diagnose the condition and assess if the patient is suitable for treatment with testosterone.
- Arrange shared care with the patient’s GP.
- Provide patient/carer with relevant (preferably written) information on use, side-effects and need for monitoring of medication.
- For injectable formulations liaise with primary care to ensure arrangements are in place for administration.
- Undertake the baseline tests and monitor serum testosterone during the initiation phase. Communicate to the GP that these have been done.
- Review results of safety monitoring and request additional tests as required. Adjust the dose as required.
- Continue to review the patient at agreed specified intervals, sending a written summary to the GP whenever the patient is reviewed.
- Monitor response to treatment and need to continue therapy.
- Provide any other advice or information for the GP if required.
Baseline tests
- Serum testosterone
- PSA & Digital rectal examination (where appropriate e.g. Males > 40 years).

Once initiation complete advise GP of any monitoring required for the following
- Serum testosterone
- PSA (where appropriate)
- FBC, LFTs and Lipids

GP Responsibilities
- Prescribe testosterone; continued prescribing is appropriate for patients attending regular review.
- For injectable formulations ensure arrangements are in place for administration.
- Report adverse drug reactions to initiating specialist and usual bodies (e.g. CHM, MHRA).
- Ensure no significant drug interactions with other medicines.
- Arrange and record monitoring if requested by specialist for the following, ensuring practice systems are in place to recall patients for blood tests.
  - Serum testosterone (preferably measured at approximately 9 am)
  - PSA (where appropriate)
  - FBC, LFTs and Lipids

Adverse Effects, Precautions and Contraindications

Contraindications: breast cancer in men, prostate cancer, history of primary liver tumours, hypercalcaemia.

Tumours: Testosterone may accelerate the progression of prostate cancer (including subclinical) and BPH. Should be used with caution in cancer patients at risk of hypercalcaemia due to bone metastases.

Caution advised with: sleep apnoea, epilepsy, migraine and thrombophilia.

Androgenic side effects include: hirsutism, male-pattern baldness, seborrhoea, acne, pruritus, excessive frequency and duration of penile erections, suppression of spermatogenesis.

Fluid retention: May cause oedema and sodium retention with or without congestive heart failure in patients suffering from severe cardiac, hepatic or renal insufficiency, or ischaemic heart disease.

Other side effects include: increased haematocrit, myalgia, arthralgia, hypertension, nausea, changes in libido, depression, nervousness, mood disturbances, cholestatic jaundice, gynaecomastia, asthenia, paraesthesia, weight gain, increased bone growth, liver tumours (rarely).

Breastfeeding and Pregnancy: Should not be used.

Common Drug Interactions
Use testosterone with caution in association with:
- Coumarins and phenidione as testosterone enhances anticoagulant effect.
- Insulin and Oral Hypoglycaemic Agents: concurrent testosterone possibly lowers blood glucose levels.
- Dutasteride and finasteride: May increase bioavailability of testosterone.

Communication
For any queries relating to this patient’s treatment with testosterone, please contact the specialist named at the top of this document.

This information is not inclusive of all prescribing information and potential adverse effects. Please refer to full prescribing data in the SPC or the BNF

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