

TESTOSTERONE (NEBIDO®) - RECOMMENDED FOR INTERIM USE

Name: generic (trade)	What it is	Date Decision last revised	Decision Status	NICE / SMC Guidance
Testosterone undecanoate (Nebido®)	Intramuscular testosterone injection	November 2011	Interim	NICE - No Guidance SMC – recommended

HMMC Recommendation:

- **Testosterone undecanoate (Nebido®) is recommended as an option for testosterone replacement therapy ONLY whilst Sustanon 250® and Testosterone Enantate (Non-proprietary) are unavailable.**
- A formal evaluation of intramuscular testosterone preparations has not been undertaken and this recommendation will be revisited when the stock availability issues have been resolved.

Why was this taken to HMMC

- There is a temporary supply problem with Sustanon 250® injection. This is because they are switching over their manufacturing site. There is no date at present as to when stock will next be available.
- In addition there may be supply shortages for the alternative intramuscular testosterone preparations testosterone enantate and Virormone®.

Additional Information

- The different licensed testosterone intramuscular injection preparations vary in costs and have different salts, doses and durations (frequency of administration) – See Appendix page 2.
- There is no specific advice on switching between testosterone salts or equivalent dosing and the licensed dose for each individual product should be used.
- Patients receiving testosterone replacement therapy should be monitored periodically for response, tolerance and adverse reactions.

HERTFORDSHIRE MEDICINES MANAGEMENT COMMITTEE

Appendix - Summary of licensed intramuscular preparations of testosterone esters

Testosterone Ester	Constituent and Strength	Licensed Dose and Frequency	Cost to Trust (Excluding VAT) (Cost per year based on maximum dose)	Cost to Primary Care (Excluding VAT) (Cost per year based on maximum dose)
Testosterone Enantate (Non-proprietary; Alliance Pharmaceuticals)	Testosterone Enantate 250mg/ml	Hypogonadism: initially 250mg every 2-3 weeks; maintenance 250mg every 3-6 weeks	£14.02 per ampoule (£42.06 for 3 ampoules) (Cost £243 per year)	£15.75 for 1ml amp, £47.26 for 3 amps (Cost £273 per year)
Nebido [®] (Bayer Plc)	Testosterone undecanoate 250mg/ml x 4ml	Hypogonadism in men over 18 years: 1g every 10-14 weeks (if necessary second dose may be given after 6 weeks)	£80 per vial (Cost £416 per year)	£80.00 for 4ml amp (Cost £416 per year)
Sustanon 250 [®] (Merck Sharpe and Dohme Limited in the UK)	Testosterone propionate 30mg, testosterone phenylpropionate 60mg, testosterone isocaproate 60mg and testosterone decanoate 100mg/ml	Androgen deficiency: 1ml ampoule every 3 weeks	£2.22 per ampoule (Cost £38.48 per year)	£2.45 for 1ml amp (Cost £42.47 per year)
Viormone [®] (Nordic Pharma Ltd)	Testosterone propionate 50mg/ml	Androgen Deficiency: 50mg 2-3 times weekly Delayed puberty: 50mg weekly Breast cancer in women: 100mg 2-3 times weekly	£4.10 per ampoule (£40.95 for 10 ampoules) (Cost £638 per year)	£4.50 for 2ml amp, £45.00 for 10x2ml amps (Cost £701 per year)

Refer to the Summary of Product Characteristics for full information:

<http://www.medicines.org.uk/emc/>