

## TESTOSTERONE UNDECANOATE (NEBIDO®) INTRAMUSCULAR INJECTION FOR THE TREATMENT OF MALE PRIMARY HYPOGONADISM IN PATIENTS AGED 18 YEARS AND OVER

### AMBER INITIATION: RECOMMENDED FOR RESTRICTED USE

NAME: GENERIC (TRADE)	WHAT IT IS	LICENSED INDICATION	DECISION LAST REVISED	DECISION STATUS	NICE GUIDANCE
Testosterone undecanoate (Nebido®)	Intramuscular testosterone injection	Treatment of male primary hypogonadism in patients aged 18 years and over	February 2019	Final	No guidance

#### **Recommendation following discussion with local specialists:**

**AMBER INITIATION: RECOMMENDED FOR RESTRICTED USE AS AN OPTION FOR THE TREATMENT OF MALE PRIMARY HYPOGONADISM IN PATIENTS AGED 18 YEARS AND OVER FOLLOWING INITIATION AND STABILISATION BY SPECIALIST.**

Nebido® (testosterone undecanoate) is used in testosterone replacement therapy for male primary hypogonadism, when testosterone deficiency has been confirmed by clinical features and biochemical tests.

- **Specialist endocrinologist to initiate, prescribe and make arrangements for the administration of the first dose within the Trust.**
- **Specialist to monitor testosterone preparation until dose stable or for 12 weeks, whichever is the longest.**
- **Following this, prescribing responsibility for 3 monthly maintenance dose (and responsibility for monitoring and administration) may be transferred to the GP.**
- **Administered by intramuscular injection usually by a nurse or doctor.**

#### **Dosing regimen and administration:**

Nebido® (testosterone undecanoate) is administered via deep intramuscular injection, 1g every 10-14 weeks. In practice this is usually every 3 months.

#### **Monitoring (see table for actions for abnormal results):**

##### **6 Months following initiation**

- Monitor Serum testosterone level, PSA, FBC and LFTs.

##### **Long term**

- Monitor FBC, renal function, hepatic function and lipid profile every 12 months.
- Serum testosterone levels should be measured annually, or if clinically indicated or as advised by specialist. Sample should be taken at the end of an injection interval i.e. 'trough' level prior to next injection is preferable (a 'peak' level can be done mid-way between injections but it is less useful when adjusting frequency).
- Prostate gland and breast examination, including digital rectal examination and serum PSA should be undertaken annually or if clinically indicated or as advised by specialist (with particular vigilance for

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those with clinical or familial risk factors).

- Ongoing: Monitor for adverse effects and development of cautions or contraindications including for oedema, symptoms of heart failure and prostatism.
- Other monitoring will be individually based on the advice of specialist.

### **Adverse effects:**

The most common side effects are injection site pain and acne. Other side effects include polycythaemia, increased haematocrit, increased red blood cell count, increased haemoglobin, weight increase, hot flushes, increased prostate specific antigen, abnormal prostate examination and benign prostate hyperplasia. See BNF/SPC for comprehensive list.

### **Action to be taken for abnormal blood results**

**West Herts Hospital Trust endocrinology specialists can be contacted via:**

[wherts-tr.endocrinology@nhs.net](mailto:wherts-tr.endocrinology@nhs.net)

**East and North Herts Trust endocrinology specialists can be contacted via:**

[diabendoadmin.enh-tr@nhs.net](mailto:diabendoadmin.enh-tr@nhs.net)

<b>ABNORMAL RESULT</b>	<b>ACTION TO BE TAKEN BY GP</b>
Testosterone levels remain less than 8.4nmol/L pre-injection dose	Consider reducing injection interval (injection interval should be within the recommended range of 10 to 14 weeks). If any queries, discuss with specialist.
Testosterone levels greater than 28.7nmol/L pre-injection dose	Consider lengthening injection interval (injection interval should be within the recommended range of 10 to 14 weeks). If any queries, discuss with specialist.
FBC (Haemoglobin) greater than 18g/dL	Discuss with specialist. Check FBC in 28 days.
FBC (Haematocrit) greater than 0.54L/L	STOP TREATMENT and refer to specialist
LFT (ALT) elevated to greater than 100IU/L	STOP TREATMENT and refer to specialist
PSA greater than 4ug/L	Exclude UTI and question patient regarding prostatic symptoms. Discuss with specialist.
Lipid profile: Cholesterol greater than 5mmol/L with HDL less than 1.0mmol/L or Triglycerides greater than 1.9mmol/L	Prior to or during Nebido® treatment – investigate and treat in context of overall health by clinician responsible. Any significant worsening of lipid profile on Nebido® should result in stopping treatment prior to further investigation. Refer to specialist.
Detection of a prostatic abnormality on digital rectal examination.	Refer to specialist
Detection of a breast abnormality on breast examination.	Refer to specialist
International Prostate Symptom Score (I-PSS) > 19	Refer to specialist
An increase in serum or plasma PSA concentration greater than 1.4ng/ml within any 12-month period of testosterone treatment.	Refer to specialist

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***This does not replace, but should be read in conjunction with the SPC<sup>1</sup>***

**Special warnings/interactions:**

Contraindications

- Testosterone undecanoate injection is not recommended for males under 18 years of age.
- Testosterone is contraindicated in androgen-dependent carcinoma of the prostate or male mammary gland; past or present liver tumours; hypersensitivity to the active substance or to any of the excipients

Cautions

- Caution should be taken in patients with cancer who are at risk of hypercalcaemia (and associated hypercalciuria) due to bone metastases. Regular monitoring of calcium is recommended in these patients.
- Caution should be exercised in those patients with latent or overt cardiac failure, renal dysfunction, hypertension, epilepsy or migraine.

Interactions

- Anticoagulants – enhances effect of coumarins and phenindione

***See Appendix 1 of the BNF or the SPC<sup>1</sup> for further details***

**References:**

1. Summary of Product Characteristics (SPC) Nebido 1000mg/4ml, solution for injection. Bayer. Last revised on the EMC, October 2018. Available online at [www.emc.medicines.org.uk](http://www.emc.medicines.org.uk)
2. Joint Formulary Committee. British National Formulary (online). London: BMJ Group and Pharmaceutical Press. Available online [www.medicinescomplete.com](http://www.medicinescomplete.com)
3. NHS Barnsley Area Prescribing Committee Shared Care Guideline for Testosterone Supplementation <http://best.barnsleyccg.nhs.uk/clinical-support/medicines/shared-care-guidelines/Testosterone%20Shared%20Care%20Guidelines.pdf>
4. Hull & East Riding Prescribing Committee Prescribing Framework for Testosterone in Adults <https://www.hey.nhs.uk/wp/wp-content/uploads/2016/03/testosterone.pdf>

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