

Press release for medical media only

THE SCOTTISH MEDICINES CONSORTIUM (SMC) APPROVES NEBIDO[▼]® FOR TESTOSTERONE DEFICIENCY SYNDROME

The SMC has accepted Nebido[▼]® (testosterone undecanoate) for use in Scotland for the treatment of hypogonadism, when testosterone deficiency has been confirmed by clinical features and biochemical tests¹. Hypogonadism, also known as Testosterone Deficiency Syndrome (TDS), describes men with low testosterone levels (below 12nmol/l) who experience one or more typical features which include erectile dysfunction (ED), loss of libido and feelings of depression²⁻⁵ (for full advice and list of symptoms see 'Notes to Editors').

TDS affects approximately one in every 200 men⁶ and one in ten men over the age of 50 years⁷. Approximately 37% of men with ED⁸ and around 50% of men with Type 2 diabetes have low testosterone levels⁹. Studies have also shown that men with low testosterone levels may have an increased risk of more serious diseases such as cardiovascular illness and Type 2 diabetes^{10,11}.

TDS can be treated effectively with testosterone therapy^{3,10}. By restoring testosterone levels to the normal range, improvements can be seen in sexual desire (libido), energy and drive, erectile function, mood, lean body mass and reductions in waist circumference^{3,10}.

Nebido is the first long-acting testosterone injection available in the UK, requiring 3-5 injections per year as maintenance therapy¹², compared with current preparations which can require up to 24 injections per year^{13,14}, minimising the disruption to patients' lives. Due to Nebido's slow release mode of action, testosterone levels are maintained within the physiological range, minimising peaks and troughs¹².

Professor Richard Anderson, Consultant in Reproductive Medicine, Edinburgh Royal Infirmary commented; *"Treatment options for men needing testosterone replacement have previously been very limited. The positive review of Nebido in Scotland by the SMC provides a convenient and effective choice for men and their doctors. It offers a longer-acting preparation with more stable testosterone levels resulting in improved treatment of symptoms and other consequences of deficiency."*

New recommendations on the identification, monitoring and treatment of hypogonadism have been formulated by major international scientific organisations,

including the European Association of Urology, the European Society of Endocrinology and the European Academy of Andrology³. These state that all patients presenting with ED, especially those with ED and Type 2 diabetes, should have their serum testosterone levels measured on a blood sample taken in the morning between 07.00 and 11.00³.

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Notes to Editors

1) Full advice from the SMC: following a full submission testosterone undecanoate (Nebido) is accepted for use within NHS Scotland as testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests¹.

Compared with alternative intramuscular preparations it offers the advantage of reduced frequency of dosing with less inter-dose fluctuation of testosterone levels¹.

2) Under real life conditions, Nebido appears to be a well tolerated and effective treatment for TDS¹⁵. In a study published at the Annual Congress of The European Association of Urology, March 2007, 92.5% of patients expressed satisfaction with the treatment¹⁵.

3) Common features of TDS include: rarely being in the mood for sex, a feeling of constant tiredness or lack of energy and impotence. Men with TDS may also experience one or more of the following features²⁻⁵:

- o Increased abdominal waist size (more than 102cm or 40" when measured just above the naval)
- o Regular feelings of depression or irritability
- o Memory loss or inability to concentrate
- o Hot flushes or sweating
- o Marked weight loss and muscle strength
- o Loss of body hair and skin alterations
- o Sleep disturbances
- o Bone fractures or low bone density

4) Contraindications include androgen-dependent prostate cancer or breast cancer.¹² Although, clinical studies have demonstrated that Nebido does not increase prostate specific antigen levels above the normal range^{16,17}.

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