Nebido® 1000 mg/4 ml, solution for injection (testosterone undecanoate) Prescribing Information
(Refer to full Summary of Product Characteristics (SmPC) before prescribing)

Presentation: 1ml of solution contains 250 mg of testosterone undecanoate, corresponding to 157.9 mg of testosterone. Each 4ml vial of solution contains 1000 mg of testosterone undecanoate. **Indication:** Testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests. **Posology and method of administration:** Strictly for intramuscular use. *Application:* Inject Nebido® extremely slowly. One vial (1000mg) is injected intramuscularly every 10 to 14 weeks. Nebido® should be injected deeply into the gluteal muscle, and must be administered very slowly. Special care should be taken to avoid intravasal injection. The contents of a vial should be injected intramuscularly immediately after opening the vial. *Starting treatment:* Measure serum testosterone levels before the start and during initiation of treatment. If appropriate, first injection interval may be reduced to a minimum of 6 weeks. *Maintenance:* Injection interval within 10 to 14 week range. Monitor serum testosterone and symptoms regularly; adjust injection interval as appropriate. ***Paediatric population*:** Not for use in children. Not evaluated clinically in males under 18. ***Geriatric patients*:** Based on limited data, no dose adjustment is considered necessary. **Contra-indications:** Androgen-dependent prostate cancer or breast cancer. Past or present liver tumours. Hypersensitivity to testosterone or any of the excipients. Not for use in women. **Warnings and precautions:** Use only if hypogonadism has been demonstrated and if other etiology has been excluded. Limited experience on the safety and efficacy in patients over 65 and no consensus about age specific testosterone reference values. Take into account that physiologically, testosterone serum levels are lower with increasing age Before therapy exclude prostate cancer. Examine prostate and breast at least annually, or twice yearly in elderly or at risk patients (clinical or familial factors). Monitor testosterone levels at baseline, and at regular intervals during treatment, and adjust individual dosage to ensure maintenance of eugonadal testosterone levels. Periodically check haemoglobin, haematocrit, liver function tests and lipid profile in long-term androgen therapy patients. Androgens may accelerate the progression of sub-clinical prostate cancer and benign prostatic hyperplasia. Use with caution in cancer patients at risk of hypercalcaemia (and associated hypercalciuria), due to bone metastases. Regular monitoring of serum calcium concentration is recommended in these patients. Rarely, liver tumours (both benign and malignant) have been reported. Include liver tumour in differential-diagnostic considerations if severe upper abdominal complaints, liver enlargement or signs of intra-abdominal haemorrhage occur. Efficacy and safety of Nebido® has not been demonstrated in patients with hepatic and renal impairment, therefore testosterone replacement therapy should be used with caution in these patients. Nebido® may cause oedema with or without congestive cardiac failure in patients with severe cardiac, hepatic or renal insufficiency, or in patients with ischaemic heart disease. In this case, stop treatment immediately. Testosterone may cause a rise in blood pressure and Nebido® should be used with caution in men with hypertension. Testosterone and derivatives have been reported to increase the activity of coumarin derived oral anticoagulants. Use with caution in patients with thrombophilia, as thrombotic events during testosterone therapy have been reported in these patients. Use with caution in patients with bleeding disorders, epilepsy, migraine and in patients predisposed to oedema. Improved insulin sensitivity may occur. Irritability, nervousness, weight gain, prolonged or frequent erections may indicate excessive androgen exposure requiring dose adjustment. Pre-existing sleep apnoea may be potentiated. Testosterone may produce a positive reaction in anti-doping tests. Not suitable for developing muscles or increasing fitness in healthy individuals. Withdraw treatment if symptoms of excessive androgen exposure persist or reappear. **Interactions:** Interactions reported with coumarin derived oral anticoagulants (requires dose monitoring), ACTH or corticosteroids, and thyroxin binding globulin in laboratory tests. **Pregnancy and lactation:** Not for use in women. **Effects on ability to drive and use machines:** None known. **Undesirable effects:** Common – injection site pain, acne, polycythaemia, haematocrit increased*, red blood cell count increased*, haemoglobin increased, increased weight, hot flush, increased prostate specific antigen, abnormal prostate examination, benign prostate hyperplasia and various injection site reactions. **Respective frequency has been observed in relation to the use in testosterone containing products.* Serious side effects – *cf. CI/Warnings and Precautions* – in addition, hypersensitivity, cardiovascular disorder, depression, aggression, hypertension, liver function test abnormalities, urinary retention, prostatic intraepithelial neoplasia and prostatitis. Pulmonary microembolism of oily solutions can in rare cases lead to signs and symptoms such as cough, dyspnoea, malaise, hyperhidrosis, chest pain, dizziness, paraesthesia or syncope. These reactions may occur during or immediately after the injection and are reversible. Suspected anaphylactic reactions after Nebido injection have been reported. Other side effects - The following adverse reactions have been reported under treatment with testosterone-containing preparations: nervousness, hostility, sleep apnoea, various skin reactions including seborrhoea, increased frequency of erections, in rare cases, priapism, and, in very rare cases, jaundice. Therapy with high doses of testosterone preparations commonly reversibly interrupts or reduces spermatogenesis, thereby reducing the size of the testicles. Prescribers should consult the SmPC in relation to

other side effects. **Overdose:** Reduce dose or terminate therapy. **Incompatibilities:** Must not be mixed with other medicinal products. **Legal Category:** POM. **Package Quantities and Basic NHS Costs:** 1 x 4ml vial (£87.11). **MA Number(s):** PL00010/0549. **Further information available from:** Bayer plc, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA, United Kingdom. Telephone: 01635 563000. **Date of preparation:** January 2017.

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Bayer plc. Tel.: 01635 563500, Fax.: 01635 563703, Email: pvuk@bayer.com