



Nebido®

Background

What is Nebido®?

Nebido® is the first long-acting injectable testosterone preparation, indicated for the treatment of male hypogonadism. Hypogonadism is a condition in which men have low levels of testosterone (serum total testosterone levels below 8 nmol/L (231 ng/dL) or 12 nmol/L (246 ng/dL), resp.)¹ and typical symptoms of testosterone deficiency syndrome. Low testosterone levels are associated with erectile dysfunction (ED) and other serious health conditions.²

Nebido® is injected every three months in long-term treatment, avoiding unphysiological peaks and troughs of serum testosterone levels in the blood stream. Following injection, Nebido® is gradually released in the body over three months. However, there is an increase of testosterone concentration just one day after injection.

Pharmacological Properties

One ampoule of Nebido® contains 1000mg of testosterone undecanoate (TU) in 4ml of castor oil for intramuscular injection. TU is an ester and is cleaved by an enzyme into natural testosterone.

Efficacy

Nebido® provides effective therapy as assessed by testosterone levels, Aging Males Symptoms Scores and metabolic parameters.³



A single application of Nebido[®] restores normal testosterone plasma levels (12–30 nmol/L) resulting in the improvement of hypogonadal symptoms, such as:

- Diminished sexual desire and erection quality/frequency
- Changes in mood and decreased cognitive function
- Sleep disturbances
- Decreased lean body mass and muscle volume/strength
- Increased visceral fat
- Decreased body hair and skin alterations
- Decreased bone and mineral density⁴

A recent large, International, multi-centre, **Post-Authorisation Surveillance Study** (IPASS) looking at testosterone replacement therapy for hypogonadal men in real life found that, in daily clinical practice, the percentage of patients who reported “low” or “very low” levels of sexual desire/libido decreased from 62 percent at baseline to 13 percent after four injections. Similar favourable changes were observed for vigour/vitality, overall mood and ability to concentrate. At baseline, 61 percent of patients had moderate, severe or extremely severe erectile dysfunction (ED), decreasing to 25 percent after Nebido[®] therapy.⁵

Safety

In the IPASS study, the incidence of adverse events (AEs) and adverse drug reactions (ADRs) was low (10% and 6% of patients, respectively); 1% of patients experienced a serious AE and no serious ADRs were reported. The most common ADRs were injection site pain (1%), increase in prostate-specific antigen, increase in haematocrit and hyperhidrosis (all <1%).

There is an ongoing debate around the link between testosterone therapy and prostate cancer. Until now, no case of prostate cancer has been observed in this ongoing study.⁶



Tolerability

Under real life conditions,⁷ Nebido[®] appears to be a well tolerated and effective treatment for male hypogonadism. In one study, 92.5% of patients expressed high satisfaction with the treatment.⁸

REFERENCES

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