

Due to regulatory changes, the content of the following Patient Information Leaflet may vary from the one found in your medicine pack. Please compare the 'Leaflet prepared/revised date' towards the end of the leaflet to establish if there have been any changes.

If you have any doubts or queries about your medication, please contact your doctor or pharmacist.



## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Nebido 1000 mg/4 ml, solution for injection**

Testosterone undecanoate

**Read all of this leaflet carefully before you are given this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

#### **In this leaflet:**

1. What Nebido is and what it is used for
2. Before you are given Nebido
3. How to use Nebido
4. Possible side effects
5. How to store Nebido
6. Further information

### **1. WHAT NEBIDO IS AND WHAT IT IS USED FOR**

Nebido contains testosterone, a male hormone, as the active ingredient. Nebido is injected into a muscle in your body. There it can be stored and gradually released over a period of time.

Nebido is used in adult men for testosterone replacement to treat various health problems caused by a lack of testosterone (male hypogonadism). These should be confirmed by two separate blood testosterone measurements and include:

- impotence
- infertility
- low sex drive
- tiredness
- depressive moods
- bone loss caused by low hormone levels

## 2. BEFORE YOU ARE GIVEN NEBIDO

### Do NOT use Nebido

- if you are allergic to testosterone undecanoate or any of the other ingredients of Nebido (see "What Nebido contains")
- if you have ever had androgen-dependent cancer or suspected cancer of the prostate or of the breast
- if you have or have ever had a liver tumour

Nebido is not intended for use in women.

Nebido is **not** for use in children and adolescents. There is no data available on the use of Nebido in males under 18 years of age.

### Take special care with Nebido

#### Tell your doctor if you have or have ever had:

- epilepsy
- heart, kidney or liver problems
- migraine
- temporary interruptions in your breathing during sleep (apnoea), as these may get worse
- cancer, as the level of calcium in your blood may need to be tested regularly
- blood clotting problems

If you are suffering from severe heart, liver or kidney disease, treatment with Nebido may cause severe complications in the form of water retention in your body sometimes accompanied by (congestive) heart failure.

#### Elderly patients (65 years or older)

There is no need for your doctor to adjust the dose if you are over 65 (see "*Medical examination/follow up*").

#### If your liver is not working

No formal studies have been performed in patients with liver impairment. You will not be prescribed Nebido if you have ever had a liver tumour (see "*Do not use Nebido*").

Nebido is **not** suitable for building muscles in healthy individuals or for increasing physical strength.

Nebido might lead to positive results in drug tests.

### Medical examination/Follow-up

Male hormones may increase the growth of prostate cancer and enlarged prostate glands (benign prostatic hypertrophy). Before your doctor injects Nebido, he/she will examine you to check that you do not have prostate cancer.

Your doctor will regularly examine your prostate and breast, especially if you are elderly. He/she will also take regular blood samples.

Following the use of hormonal substances such as androgen compounds, cases of benign (non-cancerous) and malignant (cancerous) liver tumours have been observed to occur.

## Using other medicines

Tell your doctor or pharmacist if you are using or have recently used any other medicines, including medicines obtained without a prescription. The doctor may need to adjust the dose if you are using any of the following:

- the hormone ACTH or corticosteroids (used to treat various conditions such as rheumatism, arthritis, allergic conditions and asthma): Nebido may increase the risk of water retention, especially if your heart and liver are not working properly
- tablets that thin your blood (anticoagulants)

If you are diabetic, it may be necessary to adjust your insulin.

Nebido may also affect the results of some laboratory tests (e.g. thyroid gland). Tell your doctor or the laboratory staff that you are using Nebido.

## Pregnancy and breast-feeding

Nebido is not for use in women and must not be used in pregnant or breast-feeding women.

Testosterone replacement therapy may reversibly reduce spermatogenesis.

## Driving and using machines

Nebido has no effect on your ability to drive or use machines.

## 3. HOW TO USE NEBIDO

Your doctor will inject Nebido (1 ampoule / vial) very slowly into a muscle. He/she will give you the injections every 10 to 14 weeks. This is enough to maintain sufficient testosterone levels without leading to a build-up of testosterone in the blood.

Nebido is strictly for intramuscular injection. Special care will be taken to avoid injection into a blood vessel (see "*Notes on handling the OPC (One-Point-Cut) ampoule*").

### Start of treatment

Your doctor will measure your blood testosterone levels before starting treatment and during the early stages of treatment. Your doctor may give you the second injection after only six weeks in order to quickly reach the necessary testosterone level. This will depend on your symptoms and testosterone levels.

### Maintaining your Nebido levels during treatment

The injection interval should always be within the recommended range of 10 to 14 weeks. Your doctor will measure your testosterone levels regularly at the end of an injection interval to make sure it is at the right level. If the level is too low, your doctor may decide to give you injections more often. If your testosterone levels are high, your doctor may decide to give you injections less often. Do not miss your injection appointments. Otherwise, your optimum level of testosterone will not be maintained.

If you think that the effect of Nebido is too strong or too weak, talk to your doctor.

## **If you used more Nebido than you should**

Symptoms of having too much Nebido include:

- irritability
- nervousness
- weight gain
- long-lasting or frequent erections

Tell your doctor, if you have any of these. Your doctor will inject it less often or will stop treatment.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Nebido can cause side effects, although not everybody gets them. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

The **most common side effects** are acne and pain where the injection is given.

**Common side effects** (between 1 and 10 in every 100 patients are likely to get these):

- abnormally high levels of blood cells
- weight gain
- hot flushes
- acne
- enlarged prostate and associated problems
- various reactions where the injection was given (eg pain, bruising, or irritation)

**Uncommon side effects** (between 1 and 10 in every 1000 patients are likely to get these):

- allergic reaction
- increased appetite, changes in blood test results (eg increased blood sugars or fats)
- depression, emotional disorder, insomnia, restlessness, aggression, or irritability
- headache, migraine, or tremor
- cardiovascular disorder, high blood pressure, or dizziness
- bronchitis, sinusitis, cough, shortness of breath, snoring, or voice problems
- diarrhoea, or nausea
- changes in liver test results
- hair loss, or various skin reactions (eg itching, reddening, or dry skin)
- joint pain, pain in limbs, muscle problems (eg spasm, pain or stiffness), or an increase in the blood substance creatine phosphokinase
- urinary tract disorders (eg decreased flow of urine, urinary retention, urge to pass urine at night)
- prostatic disorders (eg prostatic intraepithelial neoplasia, or hardening or inflammation of the prostate), changes in sexual appetite, painful testicles, painful, hardened or enlarged breasts, or increased levels of male and female hormones
- tiredness, general feeling of weakness, excessive sweating, or night sweats

The oily liquid Nebido may reach the lungs (pulmonary microembolism of oily solutions) which can in rare cases lead to signs and symptoms such as cough, shortness of breath, feeling generally unwell, excessive sweating, chest pain, dizziness, "pins and needles", or fainting. These reactions may occur during or immediately after the injection and are reversible.

Suspected anaphylactic reactions after Nebido injection have been reported.

In addition to the side effects listed above the following have been reported following treatment with preparations containing testosterone: nervousness, hostility, brief interruptions in breathing during

sleep, various skin reactions including dandruff and oily skin, more frequent erections, and very rare cases of yellowing of the skin and eyes (jaundice).

Treatment with high doses of testosterone preparations commonly stops or reduces sperm production, although this returns to normal after treatment ceases. Testosterone replacement therapy of poorly functioning testicles (hypogonadism) can in rare cases cause persistent, painful erections (priapism). High-dosed or long-term administration of testosterone occasionally increases the occurrences of water retention and oedema (swelling due to fluid retention).

## 5. HOW TO STORE NEBIDO

Keep out of the reach and sight of children.

This medicinal product does not require any special storage conditions.

Do not use Nebido after the expiry date which is stated on the carton and the label after "EXP". The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

### What Nebido contains

The active substance is testosterone undecanoate 250 mg/ml (corresponding to 157.9 mg testosterone). One ampoule / vial contains 1000 mg testosterone undecanoate.

The other ingredients are benzyl benzoate and refined castor oil.

### What Nebido looks like and contents of the pack

Nebido is a clear, yellowish oily liquid. The contents of the packs are:

1 brown glass ampoule / brown glass vial with 4 ml solution for injection

### Marketing Authorisation Holder and Manufacturer

#### Marketing Authorisation Holder

Bayer plc  
Bayer House  
Strawberry Hill  
Newbury  
Berkshire RG14 1JA  
United Kingdom

#### Manufacturer

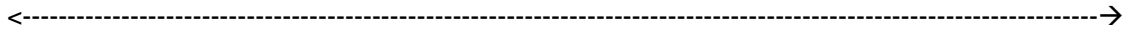
Bayer Pharma AG  
D – 13342 Berlin  
Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

- Cyprus, Czech Republic, Greece, Denmark, Estonia, Latvia, Luxembourg, Malta, Poland and Portugal: **Nebido**
- Austria: **Nebido 1000 mg/4 ml Injektionslösung**
- Belgium: **Nebido 1000 mg/4 ml, oplossing voor injectie**
- Finland: **Nebido 1000 mg/4 ml injektioneste, liuos**

- France: **Nebido 1000 mg/4 ml, solution injectable**
- Germany: **Nebido 1000 mg Injektionslösung**
- Hungary: **Nebido 250 mg/ml oldatos injekció**
- Iceland: **Nebido 1000 mg/4 ml stungulyf, lausn**
- Italy: **NEBID 1000 mg/4ml soluzione iniettabile**
- Lithuania: **Nebido 1000 mg/4 ml injekcinis tirpalas**
- Netherlands: **Nebido 1000 mg/4 ml**
- Norway: **Nebido 1000 mg/4 ml injeksjonsvæske, oppløsning**
- Slovak Republic: **Nebido 1000 mg/4 ml injekčný roztok**
- Slovenia: **Nebido 1000 mg/4 ml raztopina za injiciranje**
- Spain: **REANDRON 1000 MG/ 4 ML SOLUCIÓN INYECTABLE**
- Sweden: **Nebido, 1000 mg/4 ml injektionsvätska, lösning**
- UK and Ireland: **Nebido 1000mg/4ml, solution for injection**

**This leaflet was last revised in April 2012**



**The following information is intended for medical or healthcare professionals only:**

The solution for intramuscular injection is to be visually inspected prior to use and only clear solutions free from particles should be used.

The contents of an ampoule / vial are to be injected intramuscularly immediately after opening the ampoule / vial.

The medicinal product is for single use only and any unused solution should be discarded.

Administration

Special care must be given to avoid intravascular injection.

As with all oily solutions, Nebido must be injected strictly intramuscularly and very slowly. 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. Treatment is usually supportive, e.g. by administration of supplemental oxygen.

Suspected anaphylactic reactions after Nebido injection have been reported.

Warnings

Careful and regular monitoring of the prostate gland and breast must be performed in accordance with recommended methods (digital rectal examination and estimation of serum PSA) in patients receiving testosterone therapy at least once yearly and twice yearly in elderly patients and at risk patients (those with clinical or familial factors).

Besides laboratory tests of the testosterone concentrations in patients on long-term androgen therapy the following laboratory parameters should be checked periodically: haemoglobin, haematocrit, and liver function tests.

Notes on handling the OPC (One-Point-Cut) ampoule:

There is a pre-scored mark beneath the coloured point on the ampoule eliminating the need to file the neck. Prior to opening, ensure that any solution in the upper part of the ampoule flows down to the lower part. Use both hands to open; while holding the lower part of the ampoule in one hand, use the other hand to break off the upper part of the ampoule in the direction away from the coloured point.

