

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S5**

NEBIDO 1000 mg / 4 ml solution for injection

Testosterone undecanoate

Sugar free

Read all of this leaflet carefully before you start using NEBIDO.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, your pharmacist, nurse or other health care provider.
- NEBIDO has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What NEBIDO is and what it is used for
2. What you need to know before you use NEBIDO
3. How to use NEBIDO
4. Possible side effects
5. How to store NEBIDO
6. Contents of the pack and other 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).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE 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 certain types of cancers caused by testosterone or suspected cancer of the prostate or of the breast.
- if you have or had a liver tumour.
- if you have increased calcium levels in the blood accompanying malignant tumours.

NEBIDO is not intended for use in women.

Warning and precautions

Tell your doctor or health care provider before being given the injection:

A healthcare professional will inject NEBIDO (1 ampoule / vial) very slowly intramuscularly (into a muscle).

Drug abuse and dependence:

Always take this medicine exactly as your doctor or pharmacist has told you.

Abuse of testosterone, especially if you take too much of this medicine alone or with other anabolic androgenic steroids, can cause serious health problems to your heart and blood vessels (that can lead to death), mental health and/or the liver.

Individuals who have abused testosterone may become dependent and may experience withdrawal symptoms when the dosage changes significantly or is stopped immediately. You should not abuse this medicine alone or with other anabolic androgenic steroids because it carries serious health risks (see 'Possible Side effects').

Tell your doctor if you have or have ever had:

- oedema (fluid retention which leads to swollen legs)
- temporary interruptions in your breathing during sleep (apnoea), as these may get worse
- high blood pressure or if you are treated for high blood pressure, as testosterone may cause a rise in blood pressure.
- bleeding disorders
- thrombophilia (an abnormality of blood coagulation that increases the risk of thrombosis – blood clots in blood vessels)

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. Please inform your doctor immediately, if you notice any signs of water retention.

Medical examination/consultation

- Male hormones such as NEBIDO 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. If you are older, you may be at an increased risk for the development of prostate enlargement when using androgens like NEBIDO. Although there is no clear evidence that NEBIDO actually generate cancer of the prostate, it can enhance the growth of any existing cancer of the prostate.
- Your doctor will regularly examine your prostate, especially if you are elderly. He/she will also take regular blood samples.
- Following the use of hormonal substances such as NEBIDO, liver tumours (benign and malignant) have been observed to occur. These would present a health concern.
- In some cases, internal bleeding could occur from these tumours which might endanger life. Thus, you should always seek the immediate emergency attention of a doctor when you suffer severe stomach pains.

Additional information on special populations

Children and adolescents

NEBIDO is not indicated for use in children and adolescents.

Clinical trials with NEBIDO have so far not been conducted in children or adolescents under the age of 18.

In children and adolescents, besides causing earlier development of male secondary sex characteristics (masculinization), NEBIDO can cause accelerated growth, bone maturation, and cut short growth, thereby reducing final height. The occurrence of common acne should be expected.

Elderly patients (65 years or older)

Limited data do not suggest the need for a dosage adjustment in elderly patients (see ‘Medical examination/consultation’).

Patients with impaired liver function

No formal studies have been performed in patients with liver impairment. The use of NEBIDO is contraindicated in men with past or present liver tumors (see ‘Do not use NEBIDO’).

Patients with impaired kidney function

No formal studies have been performed in patients with kidney impairment.

Using other medicines and NEBIDO

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Medicines that may affect NEBIDO:

The doctor may need to adjust the dose if you are using any of the following:

- medicines used to treat nervousness and sleep problems (barbiturates or other enzyme inducers)
- medicines used to treat pain or inflammation (oxyphenbutazone)
- blood-thinning tablets (coumarin derived oral anticoagulants like warfarin) since this can increase your risk of bleeding. Your doctor will check the dose.
- medicines used to treat diabetes. It may be necessary to adjust the dose of your blood sugar reducing medicine. Like other androgens, testosterone may increase the effect of insulin dose or other medicines to treat diabetes.

Please be sure to inform your doctor if you suffer from an inherited or acquired disturbance of blood clotting, because this is important for your doctor to know before deciding to inject NEBIDO into a muscle.

Pregnancy, breastfeeding, fertility

NEBIDO is intended for use in men only.

Fertility

Treatment with high doses of testosterone preparations commonly may reversibly stop or reduce sperm production (see also under 'Possible side effects').

Driving and using machines

Dizziness has been reported as a less frequent side effect (see under 'Possible side effects'). If you feel dizzy, you should avoid driving and use of machines. If in doubt, talk to your doctor.

3. HOW TO USE NEBIDO

Do not share NEBIDO prescribed for you with others. Always use NEBIDO exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will inject NEBIDO (1 ampoule or 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.

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 use more NEBIDO than you should

Your doctor will determine the injection intervals in order to avoid excessively increased testosterone blood levels.

In case of accidental overdosage, no special therapeutic measure is necessary, apart from termination or dose reduction of therapy with NEBIDO.

If you forget to use NEBIDO

Please adhere to the timelines on the injection intervals agreed with your doctor for optimal efficacy of the treatment. If you missed your appointment, consult your doctor.

If you stop using NEBIDO

When NEBIDO is stopped, symptoms of testosterone deficiency may reoccur. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

NEBIDO can have side effects.

Not all side effects reported for NEBIDO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using NEBIDO, please consult your doctor, pharmacist or other health care professional for advice.

The most frequently reported side effects are acne and injection site pain.

Other side effects include:

- abnormally high levels of blood cells
- weight gain
- hot flushes
- increase in a prostate-specific antigen (increases immune response), prostate problems, increase in the size of the prostate
- various kinds of injection site reactions including pain, discomfort, itching, reddening, bruising and irritation
- increased numbers of red blood cells, increased concentration of blood cells, increased haemoglobin
- allergic reaction
- increased appetite, blood changes (increases in glycosylated haemoglobin, cholesterol or blood fats)
- depression, emotional disorder, insomnia, restlessness, aggression, or irritability
- headache, migraine or tremor
- cardiovascular disorder, high blood pressure, increased blood pressure or dizziness
- bronchitis, sinusitis, cough, shortness of breath, snoring, voice problems
- diarrhoea, nausea
- liver function test abnormal, e.g. the substance aspartate aminotransferase increased
- hair loss, skin reactions such as redness, skin rash, papular rash (raised red spots), itching or dry skin
- joint pain, pain in the hands and feet, muscle spasm, muscle strain, muscle pain, or general muscular stiffness, increased creatine phosphokinase in the blood
- decreased flow of urine, urinary retention, urge to pass urine at night, urinary tract disorder or pain in passing urine
- increase in prostate cells (prostatic intraepithelial neoplasia), a hardening of the prostate tissue, inflammation of the prostate, prostate disorder, increased appetite for sex, decrease in interest in sex, pain in the testicles, a hardening of breast tissue, breast pain, breast growth, increase in the female hormone estradiol, increase in levels of blood testosterone

- tiredness, general feeling of weakness, excessive sweating, night sweats

The oily liquid of 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, increased hair growth, 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).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of NEBIDO.

5. HOW TO STORE NEBIDO

Store all medicines out of reach of children.

Store at or below 30 °C. Protect from light.

Do not use NEBIDO after the expiry date which is stated on the label.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What NEBIDO contains

The active substance is testosterone undecanoate 250 mg/ml. One ampoule or vial contains 1000 mg testosterone undecanoate.

The other ingredients are benzyl benzoate and refined castor oil.

Bayer (Pty) Ltd

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What NEBIDO looks like and contents of the pack

NEBIDO is a clear, colourless to yellowish-brown oily liquid.

NEBIDO is packed in 1 (one) brown glass ampoule or brown glass vial closed filled with 4 ml solution for injection.

Holder of Certificate of Registration

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