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.

SKEDULERINGSTATUS **S5**

NEBIDO, 1000 mg / 4 ml oplossing vir inspuiting
Testosteroon undekanoaat
Suiker vry

Lees hierdie hele voubiljet noukeurig deur voordat u NEBIDO begin gebruik.
- Hou hierdie voubiljet. U sal dit dalk weer moet lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter, u apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- NEBIDO is aan u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al ervaar hul dieselfde simptome as u.

Wat in hierdie voubiljet is

1. Wat NEBIDO is en waarvoor dit gebruik word
2. Wat u moet weet voordat u NEBIDO gebruik
3. Hoe om NEBIDO te gebruik
4. Moontlike newe-effekte
5. Hoe om NEBIDO te bêre
6. Inhoud van die verpakking en ander inligting

1. WAT NEBIDO IS EN WAARVOOR DIT GEBRUIK WORD
NEBIDO bevat testosteroon, 'n manlike hormoon, as die aktiewe bestanddeel. NEBIDO word in 'n spier in u liggaam ingespuit. Daar kan dit gestoor word en geleidelik oor 'n tydperk vrygestel word.

NEBIDO word in volwasse mans gebruik vir testosteroonvervanging om verskeie gesondheidsprobleme te behandel, wat veroorsaak word deur 'n gebrek aan testosteroon (manlike hipogonadisme).

2. WAT U MOET WEET VOORDAT U NEBIDO GEBRUIK
Moenie NEBIDO gebruik nie:
- indien u allergies is vir testosteroon undekanoaat of enige van die ander bestanddele van NEBIDO (sien 'Wat NEBIDO bevat').
- Indien u sekere soorte kankers het wat veroorsaak word deur testosteroon, of vermoedelike kanker van die prostaat of van die bors.
- indien u 'n lewergewas het, of gehad het.
- indien u verhoogde kalsiumvlakke in die bloed het wat kwaadaardige gewasse vergesel.

NEBIDO is nie bedoel vir gebruik by vroue nie.

Waarskuwing en voorsorgmaatreëls
Lig u dokter of gesondheidsorgverskaffer in voordat u die inspuiting kry:
'n Gesondheidsorg kundige sal NEBIDO (1 ampule / flessie) baie stadig intramuskulêr (in 'n spier) inspuit.

Dwelmmisbruik en afhanklikheid:
Neem altyd hierdie medisyne presies soos u dokter of apteker u ingelig het.

Misbruik van testosteroon, veral as u te veel van hierdie medisyne alleen of met ander anaboliese androgene steroïede neem, kan ernstige gesondheidsprobleme aan u hart en bloedvate veroorsaak (wat tot die dood kan lei), verstandelike gesondheid en / of die lewer.

Individue wat testosteroon misbruik het, kan afhanklik raak en kan onttrekkingsimptome ervaar wanneer die dosis aansienlik verander of onmiddellik gestaak word. U moet nie hierdie medisyne misbruik nie, óf alleen óf met ander anaboliese androgene steroïede, omdat dit ernstige gesondheidsrisiko's dra (sien 'Moontlike newe-effekte').

Lig u dokter in indien u die volgende het, of ooit gehad het:
- edeem (vloeistofretensie wat lei tot geswelde bene).
- tydelike onderbrekings in u asemhaling tydens slaap (apnee), aangesien dit erger kan word
- hoë bloeddruk of indien u behandel word vir hoë bloeddruk, aangesien testosteroon 'n styging in bloeddruk kan veroorsaak.
- bloedingsversteurings.
- trombofilie ('n abnormaliteit van bloedstolling wat die risiko van trombose verhoog – bloedklonte in bloedvate).

Indien u aan ernstige hart-, lewer- of niersiekte ly, kan behandeling met NEBIDO ernstige komplikasies veroorsaak in die vorm van waterretensie in u liggaam, soms gepaard met (kongestiewe) hartversaking. Stel asseblief u dokter dadelik in kennis indien u enige tekens van waterretensie opmerk.

Mediese ondersoek / konsultasie
- Manlike hormone soos NEBIDO kan die groei van prostaatkanker en vergrote prostaatkliere (nie-kwaadaardige prostaathipertrofie) verhoog. Voordat u dokter NEBIDO inspuit, sal hy/sy u ondersoek om seker te maak dat u nie prostaatkanker het nie. Indien u ouer is, kan u 'n verhoogde risiko hê vir die ontwikkeling van prostaatvergroting wanneer u androgene soos NEBIDO gebruik. Alhoewel daar geen duidelike bewyse is dat NEBIDO inderdaad kanker van die prostaat veroorsaak nie, kan dit die groei van enige bestaande prostaatkanker versnel.
- U dokter sal gereeld u prostaat ondersoek, veral indien u bejaard is. Hy/sy sal ook gereelde bloedmonsters neem.
- Na die gebruik van hormonale stowwe soos NEBIDO, is lewergewasse (nie-kwaadaardig en kwaadaardig) waargeneem. Dit sal 'n gesondheidsprobleem inhou.
- In sommige gevalle kan inwendige bloeding van hierdie gewasse voorkom wat u lewe in gevaar kan stel. U moet dus altyd die onmiddellike nood-aandag van 'n dokter soek indien u erge maagpyn het.

Bykomende inligting oor spesiale bevolkings
Kinders en adolessente
NEBIDO is nie aangedui vir gebruik by kinders en adolessente nie.

Kliniese studies met NEBIDO is tot dusver nie by kinders of adolessente onder die ouderdom van 18 jaar uitgevoer nie.

By kinders en adolessente kan NEBIDO, buiten die vroeëre ontwikkeling van manlike sekondêre geslagseienskappe (manlikheid), ook versnelde groei en beenrypwording veroorsaak en groei kort knip, waardeur die finale lengte verminder word. Die voorkoms van algemene aknee moet verwag word.

Bejaarde pasiënte (65 jaar of ouer)
Beperkte data dui nie op die behoefte aan 'n dosisaanpassing by bejaarde pasiënte nie (sien 'Mediese ondersoek/konsultasie').

Pasiënte met verswakte lewerfunksie
Geen formele studies is uitgevoer by pasiënte met lewerinkorting nie. Die gebruik van NEBIDO is teenaangedui by mans met vorige of huidige lewergewasse (sien 'Moenie NEBIDO gebruik nie').

Pasiënte met verswakte nierfunksie
Geen formele studies is uitgevoer by pasiënte met nierinkorting nie.

Gebruik van ander medisyne en NEBIDO
Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)

Medisyne wat NEBIDO kan beïnvloed:
Die dokter sal dalk die dosis moet aanpas indien u enige van die volgende gebruik:
- medisyne wat gebruik word om senuweeagtigheid en slaapprobleme te behandel (barbiturate of ander ensiem-induseerders).
- medisyne wat gebruik word om pyn of inflammasie te behandel (oksifenbutasoon).
- bloedverdunnende tablette (kumarien-afgeleide orale antikoagulante soos warfarien) aangesien dit u risiko van bloeding kan verhoog. U dokter sal die dosis nagaan.
- medisyne wat gebruik word om diabetes te behandel. Dit mag nodig wees om die dosis van u bloedsuikerverlagende medisyne aan te pas. Soos ander androgene, kan testosteroon die effek van insuliendosis of ander medisyne om diabetes te behandel, verhoog.

Maak asseblief seker dat u dokter in kennis gestel is indien u aan 'n oorgeërfde of verworwe versteuring van bloedstolling ly, aangesien dit belangrik is vir u dokter om te weet voor die besluit om NEBIDO in 'n spier in te spuit.

Swangerskap, borsvoeding, vrugbaarheid
NEBIDO is slegs bedoel vir gebruik by mans.

Vrugbaarheid
Behandeling met hoë dosisse testosteroon-preparate kan gewoonlik spermproduksie omkeerbaar stop of verminder (sien ook onder 'Moontlike newe-effekte').

Bestuur en gebruik van masjinerie
Duiseligheid is aangemeld as 'n minder algemene newe-effek (sien onder 'Moontlike newe-effekte'). Indien u duiselig voel, moet u dit vermy om te bestuur en masjinerie te gebruik. Indien u twyfel, raadpleeg u dokter.

3. HOE OM NEBIDO TE GEBRUIK
Moenie NEBIDO wat aan u voorgeskryf is, met ander deel nie. Gebruik altyd NEBIDO presies soos u dokter of apteker vir u gesê het. Raadpleeg u dokter of apteker indien u nie seker is nie.

U dokter sal NEBIDO (1 ampule of flessie) baie stadig in 'n spier inspuit. Hy/sy sal die inspuitings elke 10 tot 14 weke in u spuit. Dit is genoeg om voldoende testosteroonvlakke te handhaaf sonder om te lei tot 'n opbou van testosteroon in die bloed.

NEBIDO is streng vir binnespierse inspuiting. Spesiale sorg sal toegepas word om toediening in 'n bloedvat te vermy.

Begin van behandeling

- U dokter sal u bloedtestosteroonvlakke meet voordat u met die behandeling begin, en gedurende die vroeë stadiums van die behandeling.
- U dokter kan u die tweede inspuiting na slegs ses weke gee om vinnig die nodige testosteroonvlak te bereik.
- Dit sal afhang van u simptome en testosteroonvlakke.

Handhawing van u NEBIDO-vlakke tydens behandeling

- Die inspuitingsinterval moet altyd binne die aanbevole reeks van 10 tot 14 weke wees.
- U dokter sal u testosteroonvlakke gereeld meet aan die einde van 'n inspuitingsinterval om seker te maak dit is op die regte vlak.
- Indien die vlak te laag is, kan u dokter besluit om u meer gereeld inspuitings te gee.
- Indien u testosteroonvlakke hoog is, kan u dokter besluit om u minder gereeld inspuitings te gee.
- Moenie u inspuiting-afsprake misloop nie. Andersins sal u optimale vlak van testosteroon nie gehandhaaf word nie.
- Indien u dink dat die effek van NEBIDO te sterk of te swak is, raadpleeg u dokter.

Indien u meer NEBIDO gebruik indien wat u moes

U dokter sal die inspuitingsintervalle bepaal om oormatige verhoogde testosteroonbloedvlakke te vermy.

In die geval van toevallige oordosering is geen spesiale terapeutiese maatreël nodig nie, behalwe beëindiging of dosisvermindering van terapie met NEBIDO.

Indien u vergeet om NEBIDO te gebruik

Hou asseblief by die tydlyne van die inspuitingsintervalle wat met u dokter ooreengekom is vir optimale doeltreffendheid van die behandeling. Indien u afspraak gemis is, raadpleeg u dokter.

Indien u ophou om NEBIDO te gebruik

Wanneer NEBIDO gestaak word, kan simptome van testosteroontekort weer voorkom. Indien u enige verdere vrae het oor die gebruik van hierdie medisyne, raadpleeg u dokter of apteker.

4. MOONTLIKE NEWE-EFFEKTE

NEBIDO kan newe-effekte hê.

Nie alle newe-effekte wat vir NEBIDO aangemeld word, is in hierdie voubiljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige ongewenste gevolge ervaar terwyl u NEBIDO gebruik, raadpleeg asseblief u dokter, apteker of ander gesondheidsorg kundige vir advies.

Die newe-effekte wat die meeste aangemeld word, is aknee en pyn op die inspuitplek.

Ander newe-effekte sluit in:

- abnormaal hoë vlakke van bloedselle
- gewigstoename
- warm gloede

- toename in 'n prostaatspesifieke antigeen (verhoog immuun-reaksie), prostaatprobleme, toename in die grootte van die prostaat
- verskillende soorte reaksies op die inspuitplek, insluitend pyn, ongemak, jeukerigheid, rooiheid, kneusplekke en irritasie
- verhoogde getalle rooibloedselle, verhoogde konsentrasie bloedselle, verhoogde hemoglobien
- allergiese reaksie
- verhoogde eetlus, bloedveranderinge (toename in glikosileerde hemoglobien, cholesterol of bloedvette)
- depressie, emosionele versteuring, slapeloosheid, rusteloosheid, aggressie of prikkelbaarheid
- hoofpyn, migraine of bewing
- kardiovaskulêre afwyking, hoë bloeddruk, verhoogde bloeddruk of duiseligheid
- bronchitis, sinusitis, hoes, kortasem, snork, stemprobleme
- diarree, naarheid
- lewerfunksie toets abnormaal, bv. die stof aspartaat aminotransferase verhoog
- haarverlies, velreaksies soos rooiheid, veluitslag, papillêre uitslag (verhoogde rooi kolle), jeukerigheid of droë vel
- gewrigspyn, pyn in die hande en voete, spierspasma, spierspanning, spierpyn of algemene spierstyfheid, verhoogde kreatienfosfokinase in die bloed
- verminderde vloei van urien, urienretensie, drang om snags te urineer, urienwegversteuring of pyn tydens urinering
- toename in prostaatselle (prostaat intra-epiteliale neoplasie), 'n verharding van die prostaatweefsel, inflammasie van die prostaat, prostaatversteuring, verhoogde drang na seks, afname in belangstelling in seks, pyn in die testikels, 'n verharding van borsweefsel, borspyn, borsgroei, toename in die vroulike hormoon estradiool, toename in vlakke van bloedtestosteroon
- moegheid, algemene gevoel van swakheid, oormatige sweet, nagsweet

Die olierige vloeistof van NEBIDO kan die longe bereik (pulmonale mikro-embolisme van olierige oplossings) wat in seldsame gevalle kan lei tot tekens en simptome soos hoes, kortasem, algemene ongesteldheid, oormatige sweet, borspyn, duiseligheid, "naalde-en-spelde" of floute. Hierdie reaksies kan tydens of onmiddellik na die inspuiting voorkom en is omkeerbaar.

Vermoedelike anafilaktiese reaksies na NEBIDO-inspuiting is aangemeld.

Benewens die newe-effekte hierbo gelys, is die volgende aangemeld na behandeling met preparate wat testosteroon bevat: senuweeagtigheid, vyandigheid, kort onderbrekings in asemhaling tydens slaap, verskeie velreaksies, insluitend skilfers en olierige vel, verhoogde haargroei, meer gereelde ereksies, en baie seldsame gevalle van vergeling van die vel en oë (geelsug).

Behandeling met hoë dosisse testosteroon-preparate stop of verminder gewoonlik spermproduksie, hoewel dit terugkeer na normaal nadat die behandeling gestaak is. Testosteroon-vervangingsterapie van swak funksionerende testikels (hipogonadisme) kan in seldsame gevalle aanhoudende, pynlike ereksies (priapisme) veroorsaak. Hoë dosisse of langtermyn-toediening van testosteroon verhoog soms die voorkoms van waterretensie en edeem (swelling as gevolg van vloeistofretensie).

Indien u enige newe-effekte opmerk wat nie in hierdie voubiljet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte
Indien u newe-effekte evraar, raadpleeg u dokter, apteker of verpleegkundige. U kan ook newe-effekte by SAHPRA aanmeld via die vorm "**6.04 Adverse Drug Reaction Reporting Form**", wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van NEBIDO te verskaf.

5. HOE OM NEBIDO TE BÊRE

Bêre alle medisyne buite bereik van kinders.
Bêre teen of benede 30 °C. Beskerm teen lig.
Moenie NEBIDO gebruik ná die vervaldatum wat op die etiket vermeld word nie.
Medisyne moet nie via afvalwater of huishoudelike afval weggegooi word nie. Vra u apteker hoe om van medisyne ontslae te raak wat nie meer benodig word nie.

6. INHOUD VAN DIE VERPAKKING EN ANDER INLIGTING

Wat NEBIDO bevat
Die aktiewe bestanddeel is testosteroon undekanoaat 250 mg/ml. Een ampule of flessie bevat 1000 mg testosteroon undekanoaat.

Die ander bestanddele is bensielbensoaat en verfynde kasterolie.

Hoe NEBIDO lyk en inhoud van die verpakking
NEBIDO is 'n helder, kleurlose tot geelbruin olierige vloeistof.

NEBIDO is verpak in 1 (een) bruin glas-ampule of bruin glas-flessie geslote-gevul met 4 ml oplossing vir inspuiting.

Houer van Registrasiesertifikaat
Adcock Ingram Limited
New Road 1,
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Midrand, 1685
Kliëntediens: 0860 ADCOCK / 232625

Hierdie voubiljet is mees onlangs hersien op
02 Augustus 2022

Registrasienommer
A38/21.7/0641

Namibië: NS3 06/21.7/0228

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 generates 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 (masculinisation), 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.

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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