PATIENT INFORMATION LEAFLET FOR

SCHEDULING STATUS: S4

NUXTAND 40 mg Soft gelatine capsules

Enzalutamide 40 mg.

Contains sugar: Sorbitol 61, 671 mg per capsule

Read all of this leaflet carefully before you start taking NUXTAND

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- NUXTAND 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

6. Contents of the pack and other information

1. What NUXTAND is and what it is used for

NUXTAND contains the active ingredient enzalutamide, and it is used in adult men for the treatment of prostate cancer that has spread to other parts of the body other than the prostate.

2. What you need to know before you take NUXTAND

Do NOT take NUXTAND

- If you are allergic to enzalutamide or any of the other ingredients of NUXTAND (listed in **section 6**).
- If you are a woman.

Warnings and precautions

Special care should be taken with NUXTAND :

- If you have a history of seizures.
- If you are at high risk of getting seizures (fits).
- If you are taking medicines such as warfarin.
- If you have been diagnosed with severe kidney disease.
- If you have been diagnosed with severe liver disease.
- If you are at high risk of getting any type of heart disease.
- If you are on chemotherapy.

Tell your doctor:

- If you develop symptoms such as fits, headaches, confusion, blindness or other visual problems and increased blood pressure while taking NUXTAND .
- If you develop a rash or swelling of the face, tongue or lip.

Children and adolescents

NUXTAND is not suitable for use in children as prostate cancer is not present in children.

Other medicines and NUXTAND

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

The following medicines may increase the effect of NUXTAND :

- Gemfibrozil (used to treat cholesterol).

The following medicines may reduce the effects of NUXTAND :

- Rifampicin (used to treat tuberculosis (TB)).

NUXTAND may reduce the effect of the following medicines:

- Midazolam, Diazepam and Zolpidem (used to treat anxiety and sleeplessness)
- Warfarin (used to prevent the formation of blood clots)
- Tramadol and Fentanyl (used in the management of severe pain)

- Clarithromycin and Doxycycline (antibiotics used for the treatment of infections)
- Cabzitaxel (used in the treatment of cancer)
- Phenobarbitone. Phenytoin, Carbamazepine, Clonazepam, Phenytoin, Primodone and Valproic acid (used to treat epilepsy)
- Diltiazem, Felodipine, Nicardipine, Nifedipine and Verapamil (used to treat heart conditions and increased blood pressure)
- Colchicine (used to treat gout, may require a dose adjustment)
- Digoxin (used to treat heart conditions)
- Dexamethasone and Prednisolone (commonly used corticosteroids)
- Indinavir and Ritonavir (used in the treatment of HIV)
- Tacrolimus (used to reduce the response of your immune system)
- Omeprazole (used to treat ulcers and heartburn)
- Atorvastatin and Simvastatin (used to treat cholesterol)
- Levothyroxine (used to treat thyroid conditions)

NUXTAND may increase the effect of the following medicines:

- Methotrexate (used in the treatment of cancer and rheumatoid arthritis)

When NUXTAND is used together with the following medicines, in may increase the risk of heart related side effects:

- Quinidine, Disopyramide, Amiodarone, Sotalol, Dofetilide and Ibutilide (used to treat abnormal heart rhythm)
- Methadone (used for the management of pain)

- Moxifloxacin (an antibiotic used for bacterial infections)
- Antipsychotic medicines such as risperidone

NUXTAND with food

Food does not affect exposure to NUXTAND .

Pregnancy, breastfeeding and fertility

Pregnancy

NUXTAND is not for use in women.

Contraception in males and females

You should use a condom during and for 3 months after treatment with NUXTAND if you are engaged in sexual activity with a pregnant woman.

If you engage in sexual intercourse with a woman who could potentially become pregnant, a condom and another form of birth control must be used during and for 3 months after treatment.

Breastfeeding

Since NUXTAND is not for use in women, it is not known whether or not it passes into human milk.

Fertility

NUXTAND may affect fertility in men.

Driving and using machines

NUXTAND may cause seizures (fits) and other side effects that may impact your ability to drive and use machines. You should not drive or use any machines until you are aware of the measure to which NUXTAND affects you.

NUXTAND contains glycerol and sorbitol

NUXTAND contains glycerol which may cause headache, an upset stomach and diarrhoea.

NUXTAND also contains sorbitol, therefore you should not take this medicine if you have been told by your doctor that you cannot tolerate certain sugars. Sorbitol may also cause an upset stomach and a mild laxative effect.

3. How to take NUXTAND

Do not share medicines prescribed for you with any other person.

Always take NUXTAND exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is 160 mg daily (four NUXTAND capsules) taken as a single dose.

If you take more NUXTAND than you should

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison center.

After an overdose of NUXTAND , you may be at an increased risk of seizures (fits).

If you forget to take NUXTAND

If you forget to take your dose of NUXTAND at the usual time, you should take the dose as close as possible to the usual time. If you forget to take your dose of NUXTAND for a whole day, you should continue with the usual daily dose on the next day. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

NUXTAND can have side effects.

Not all side effects reported for NUXTAND are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NUXTAND , please consult your health care provider for advice.

If any of the following happens, stop taking NUXTAND and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- Any heart related side effects such as chest pain.

These are all very serious side effects. If you have them, you may have had a serious reaction to NUXTAND . You may need urgent medical attention or hospitalisation.

Other side effects of NUXTAND :

Frequent side effects:

- Anxiety (feelings of worry or fear),
- Headache,
- Memory problems,
- Loss of memory,
- Disturbances in attention,
- An irresistible urge to move your legs,
- Ischemic heart disease,
- Hot flushes,
- Increased blood pressure,
- Dry skin,
- Fractures,
- Enlargement of the breasts,
- Weakness,
- Feeling tired,
- Falling.

Less frequent side effects:

- A reduction in white blood cells (determined through blood tests),
- Seeing things that are not there (hallucinations),
- Difficulties with learning,
- Seizures (fits).

Side effects where the frequency is unknown:

- A low number of platelets in the blood,
- The urge to vomit (nausea),
- Vomiting,
- Diarrhoea,
- Painful muscles,
- Muscle spasm,
- Muscle weakness,
- Back pain.

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 or 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 or to Cipla Medpro (Pty) Ltd. by email: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of NUXTAND .

5. How to store NUXTAND

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep container tightly closed.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

The active substance in NUXTAND is enzalutamide.

The other ingredients are: Butyl Hydroxy Anisole, Butyl Hydroxy Toluene, Caprylocaproyl Polyoxylglycerides (Labrasol ALF), Gelatin (Gelita RXL), Glycerin, Sorbitol sorbitan solution (Sorbitol special), Medium Chain Triglyceride (Miglyol 812 N), Purified water, Titanium dioxide, Ferric oxide Red.

What NUXTAND looks like and contents of the pack

NUXTAND is packed in HDPE bottle with a child resistant cap containing 120's capsules.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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RSA

Customer Care: 080 222 6662

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Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER: The QR Code to be generated and included after approval.