PATIENT INFORMATION LEAFLET FOR PROTYGA

SCHEDULING STATUS: S4

PROTYGA 250 mg uncoated tablets

Abiraterone acetate

Contains sugar (lactose monohydrate, 150 mg)

Read all of this leaflet carefully before you start taking PROTYGA.

- 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.
- PROTYGA 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 PROTYGA is and what it is used for

PROTYGA contains a medicine called abiraterone acetate. PROTYGA is intended for the treatment of prostate cancer that has spread to other parts of the body.

2. What you need to know before you take PROTYGA

Do not take PROTYGA:

- If you are hypersensitive (allergic) to abiraterone acetate or any of the other ingredients of PROTYGA (listed in section 6).
- If you are pregnant, trying to get pregnant or may potentially be pregnant, suspect that you are pregnant or if you are breastfeeding your baby (see **Pregnancy and breastfeeding**).
- If you have severe liver problems.
- If you are a woman. PROTYGA is for use in male patients only.
- If you are taking rifampicin (an antibiotic medicine).
- In combination with Radium 223 (which is used to treat prostate cancer).

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking PROTYGA.

Warnings and Precautions

Take special care with PROTYGA:

- Women (or health care professionals) who are pregnant or may be pregnant should not handle PROTYGA without gloves.

Talk to your doctor or pharmacist:

- If you have high blood pressure or heart failure.
- If your potassium levels are low. Low potassium levels may increase the risk of your heart beating faster, slower or irregularly.
- If you have swelling in your feet, ankles or legs due to fluid retention.
- If you recently had a heart attack.
- If you have chest pain (angina) or heart problems.
- If you have an irregular or rapid heartbeat.
- If you have kidney problems.
- If you have liver problems.

- If you experience symptoms such as yellowing of the skin or eyes, darkening of your urine, nausea (feeling sick), and vomiting (being sick) while taking PROTYGA, you should stop taking PROTYGA immediately and consult your doctor. These are symptoms of acute liver failure which can lead to death.
- PROTYGA may affect your liver and you may not have any symptoms. While you are taking PROTYGA, your doctor will check your blood to look for any effects on your liver.
- If you are taking PROTYGA while receiving therapy to reduce hormone (androgen) levels, you may be at a higher risk of being diagnosed with a build-up of fat in the liver (non-alcoholic fatty liver disease).
- If you experience possible effects on your bones such as fractures.
- If you have taken a medicine known as ketoconazole in the past for prostate cancer.
- If you have high blood sugar (diabetes).
- If you experience a reduced sex drive.
- If you have anaemia (reduced red blood cell count). Signs of anaemia may include pale skin, feeling tired or weak, shortness of breath.
- If you have muscle pain or muscle weakness.
- PROTYGA must not be given in combination with Radium 223 due to a possible increase in the risk of bone fracture or death. If you plan to take Radium 223 following treatment with PROTYGA and prednisone/prednisolone, you must wait 5 days before starting treatment with Radium 223.

Children and adolescents

PROTYGA is not for use in children and adolescents.

If PROTYGA is accidentally ingested by a child, go to the hospital immediately and take this patient leaflet with you to show the emergency doctor.

Other medicines and PROTYGA

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

This is important because PROTYGA may increase the effects of a number of medicines including heart medicines, tranquilisers, herbal medicines and others. Your doctor may want to change the dose of these medicines.
Also, some medicines may increase or decrease the effects of PROTYGA. This may lead to side effects or to PROTYGA not working as well as it should.

Tell your doctor or pharmacist if you are currently using medicines:

- to treat heart rhythm problems (such as propafenone, flecainide, metoprolol, propranolol, quinidine, disopyramide, amiodarone and sotalol).
- to treat nervous, emotional and/or mental conditions, such as schizophrenia (e.g. paroxetine, haloperidol, venlafaxine, risperidone and antipsychotics, St. John's wortand phenobarbitone).
- to treat pain (such as codeine, oxycodone and tramadol), methadone (used for pain relief and part of drug addiction detoxification).
- to treat seizures (e.g. phenytoin and carbamazepine)..
- to treat bacterial infections, such as antibiotics (rifampicin, rifabutin, rifapentine, moxifloxacin)
- that prevent your body from absorbing too much salt and keep your potassium levels from getting too low (e.g. spironolactone).

PROTYGA not with food or drink

PROTYGA must not be taken with food.
Taking PROTYGA with food causes more of PROTYGA to be absorbed by the body than is needed and this may cause serious side effects.

Pregnancy and breastfeeding

PROTYGA is not for use in women.

Do not take PROTYGA if you are pregnant or breastfeeding. It may cause harm to your unborn child if you take it when you are pregnant. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking PROTYGA.

If you are a woman of child-bearing age, are pregnant or suspect that you are pregnant (including health care professionals), you should wear gloves if you need to touch or handle PROTYGA.

Men on treatment with PROTYGA must always use a condom if their partners are of child-bearing age, and non-pregnant partners of child-bearing age should use effective contraception. Pregnant partners should use a female condom.

Men who might want to father a child should consider storing sperm since PROTYGA may lower fertility.

Driving and using machines

PROTYGA may affect your ability to drive and use machines. You should not drive, operate machinery, or do anything else that requires your attention until you know how PROTYGA affects you.

PROTYGA contains lactose and sodium

PROTYGA contains lactose monohydrate which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking PROTYGA.

PROTYGA also contains 80 mg sodium (main component of cooking/table salt) in a

four-tablet daily dose. This is equivalent to 4 % of the recommended maximum daily dietary intake of sodium for an adult and should be taken into consideration if you are on a controlled sodium diet.

3. How to take PROTYGA

Do not share medicines prescribed for you with any other person.
Always take PROTYGA exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults:

The usual dose is 4 tablets as a single dose, daily.
PROTYGA must not be taken with food. You should take PROTYGA on an empty stomach at least one hour before or at least two hours after eating.
Swallow the tablets whole with water.

PROTYGA is taken with a medicine called prednisone or prednisolone.
Take the prednisone or prednisolone exactly as your doctor has instructed you.
The usual dose is 10 mg daily.

Your doctor will tell you how long your treatment with PROTYGA will last. Do not stop your treatment without discussing it with your doctor first.
If you have the impression that the effect of PROTYGA is too strong or too weak, tell your doctor or pharmacist.

If you take more PROTYGA than you should:

In the event of an overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre. Take this leaflet and the remaining PROTYGA with you so the doctor will know what you have taken (also see section on **Children and adolescents**).

If you forget to take PROTYGA:

If you have missed your dose of PROTYGA and/or prednisone or prednisolone by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take PROTYGA and/or prednisone or prednisolone at the next regularly scheduled time. Do not take a double dose to make up for the forgotten individual doses.

If you stop taking PROTYGA:

Do not stop taking PROTYGA unless your doctor tells you to.

4. Possible side effects

PROTYGA can have side effects.

Not all side effects reported for PROTYGA are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking PROTYGA, please consult your health care provider for advice.

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

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Severe infection called sepsis (symptoms include fever, difficulty breathing, low

blood pressure, fast heart rate and mental confusion).

- Heart failure (shortness of breath, fatigue and weakness, swelling of your legs, ankles and feet, persistent cough or wheezing with white or pink blood-tinged phlegm).
- Chest pain or uncomfortable feeling in your chest, often spreading to your arms or neck and sometimes to your shoulders and back which may be signs of a problem with your heart.
- Changes in the way your heart beats (beating faster, slower or irregular).
- Heart attack, changes in ECG - electrocardiogram (QT prolongation).
- Disease of the liver, failure of the liver to function (also called acute liver failure) which may cause yellowing of your skin and whites of the eyes (jaundice), nausea, vomiting and a general sense of feeling unwell.
- Kidney failure, which may cause symptoms such as passing less urine than is normal for you, leading to fluid retention with swelling of your legs, ankles and feet.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Muscle weakness, muscle twitches or a pounding heart beat (palpitations). These may be signs that the level of potassium in your blood is too low.
- A high level of a certain type of fat (triglycerides) in the blood (yellowish deposits of fat on or around your eyelids).
- Bladder infections (pain or burning when urinating).
- High blood pressure.
- Diarrhoea and indigestion.
- Increased liver enzymes when your blood is tested and abnormal liver function

(pain or swelling in the abdomen, nausea and vomiting, dark urine).

- Skin rash.
- Presence of blood in your urine.
- Swelling of your hands, legs and/or feet due to retained fluid.
- Bone fractures.

Less frequent side effects:

- Adrenal gland problems (pain in your muscles and joints, low blood pressure making you dizzy when standing up, cravings for salt).
- Lung irritation (also called allergic alveolitis) which may lead to tightness in the chest, a dry cough, and shortness of breath.
- Swollen joints, muscle weakness and/or muscle pain.

Side effect of unknown frequency:

- Fat build-up in the liver (non-alcoholic fatty liver disease).

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.

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 PROTYGA.

5. How to store PROTYGA

Store at or below 25 °C.

Store all medicines out of reach of children.

Do not use after the expiry date printed on the container.

Women of child-bearing age, pregnant women or those who may potentially be pregnant must use protection (e.g. gloves) when handling PROTYGA.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What PROTYGA contains

The active substance is abiraterone acetate 250 mg.

The other ingredients are colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, sodium lauryl sulphate.

What PROTYGA looks like and contents of the pack

PROTYGA tablets are white to off-white, oval shaped tablets, debossed with “A” on one side and “250” on the other side.

PROTYGA is contained in HDPE round opaque white/off-white bottles with 38 mm child resistance closure with heat seal and pulp liner for induction seal.

Pack size: 120 tablets.

Holder of certificate of registration

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