PROPOSED CLEAN Patient information Leaflet:
Dr. Reddy's Laboratories (Pty) Ltd.
TERONRED 500 (film-coated tablets)
Seq: 0006

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

TERONRED 500, 500 mg, film-coated tablets

Abiraterone acetate

Contains sugar (lactose monohydrate)

Each film-coated tablet contains 245 mg of lactose monohydrate and 11,69 mg of sodium.

Read all of this leaflet carefully before you start taking TERONRED 500

- 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.
- TERONRED 500 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 TERONRED 500 is and what it is used for
2. What you need to know before you take TERONRED 500
3. How to take TERONRED 500
4. Possible side effects
5. How to store TERONRED 500
6. Contents of the pack and other information

1. What TERONRED 500 is and what it is used for

TERONRED 500 contains a medicine called abiraterone acetate.

TERONRED 500 belongs to a group of medicines called hormone inhibitors.

It is used to treat prostate cancer in adult men that has spread to other parts of the body. It stops your body from making testosterone, which can then slow down the growth of prostate cancer.

2. What you need to know before you take TERONRED 500

Do not take TERONRED 500

- if you are allergic (hypersensitive) to abiraterone acetate or any of the other ingredients of TERONRED 500 (listed in section 6).
- if you are pregnant or might be pregnant or are trying to get pregnant (see Pregnancy and breastfeeding). If you are pregnant or might be pregnant, you should wear gloves if you need to touch or handle TERONRED 500.
- if you are breastfeeding.
- if you are a woman. TERONRED 500 is for use in male patients only.
- if you have moderate to severe liver damage.
- if you are taking a medicine called rifampicin.
- in combination with Ra-223 (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 TERONRED 500.

Warnings and precautions

Special care should be taken with TERONRED 500:

Tell your doctor or pharmacist before taking TERONRED 500:

- if you have liver problems
- if you have been told you have high blood pressure or heart failure or low blood potassium (low blood potassium may increase the risk of heart rhythm problems)
- if you have had other heart or blood vessel problems
- if you have an irregular or rapid heart rate
- if you have suffered from a heart attack
- if you are taking a medicine called digoxin
- if you have shortness of breath
- if you suffer from chest pain
- if you have gained weight rapidly
- if you have swelling in the feet, ankles, or legs
- if you have kidney problems
- about the need to take this medicine with prednisone or prednisolone

- if you have problems with your bones such as decreased bone density
- if you have taken a medicine known as ketoconazole in the past for prostate cancer
- if you have high blood sugar / diabetes
- if you are on chemotherapy
- if you are on certain types of medication which interact with TERONRED 500.

Tell your doctor if you have been told you have any heart or blood vessel conditions, including heart rhythm problems, or are being treated with medicines for these conditions.

Tell your doctor if you have yellowing of the skin or eyes, darkening of the urine, or severe nausea or vomiting, as these could be signs or symptoms of liver problems. Rarely, failure of the liver to function (called acute liver failure) may occur, which can lead to death.

Tell your doctor if you require vaccination or have come into contact with someone who has received a vaccine.

Tell your doctor if you have tuberculosis and/or HIV.

Androgen deprivation therapy (ADT), such as TERONRED 500, is associated with an increased risk of developing non-alcoholic fatty liver disease (NAFLD) and other liver conditions (such as cirrhosis (scarring), liver necrosis (cell death)).

Non-alcoholic fatty liver disease or NAFLD is when there is accumulation of excess fat in the liver of patients who drink little or no alcohol.

Decrease in red blood cells may occur. –Tell your doctor if you start feeling tired and weak, have pale skin, suffer from shortness of breath, chest pain, get frequent infections, headaches, or feel dizzy (this could mean you may have anaemia).

Reduced sex drive (libido), muscle weakness and/or muscle pain may occur.

TERONRED 500 must not be given in combination with Ra-223 due to a possible increase in

the risk of bone fracture or death.

If you plan to take Ra-223 following treatment with TERONRED 500 and prednisone/prednisolone, you must wait 5 days before starting treatment with Ra-223.

If you have diabetes, your blood sugar may drop if you take TERONRED 500 plus prednisone/prednisolone with some medicines for diabetes such as pioglitazone or repaglinide. Tell your healthcare provider if you monitor your blood sugar while taking a medicine for diabetes and notice a drop in your blood sugar.

Blood monitoring

TERONRED 500 may affect your liver, and you may not have any symptoms. When you are taking TERONRED 500, your doctor will check your blood periodically to look for any effects on your liver.

Children and adolescents

TERONRED 500 is not for use in children and adolescents. If TERONRED 500 is accidentally ingested by a child or adolescent, go to the hospital immediately and take the package leaflet with you to show the emergency doctor.

Other medicines and TERONRED 500

Always tell your healthcare provider if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Tell your doctor if you are taking the following:

- antibiotics used to treat TB (tuberculosis) e.g., rifampicin, rifabutin and rifapentine. Do not take TERONRED 500 if you are taking rifampicin.
- moxifloxacin (an antibiotic)
- medicines used to treat seizures (fits) e.g. phenytoin, carbamazepine, phenobarbitone

- herbal medicine (St John's Wort [*Hypericum perforatum*])
- medicines containing dextromethorphan (cough suppressant)
- medicines used to treat high blood pressure and heart pain (angina) e.g., metoprolol
- medicines used to treat heart rhythm problems e.g., propranolol, propafenone, flecainide, amiodarone, sotalol, dofetilide, ibutilide, quinidine, disopyramide
- medicines used to treat mental illness e.g., paroxetine, desipramine, venlafaxine, haloperidol, risperidone and other antipsychotics
- medicine used to treat high blood sugar (diabetes) e.g., pioglitazone and repaglinide
- medicines used to treat pain e.g. methadone, codeine, oxycodone and tramadol
- spironolactone (a medicine used to treat heart failure and high blood pressure).

TERONRED 500 with food and drink

- TERONRED 500 must not be taken with food (see section 3, "HOW TO TAKE TERONRED 500").
- Taking TERONRED 500 with food may cause side effects.

Pregnancy, breastfeeding and fertility

TERONRED 500 is not for use in women.

- **TERONRED 500 may cause harm to the unborn child if it is taken by women who are pregnant.**
- If you are pregnant or breastfeeding or may be pregnant you should wear gloves if you need to touch or handle TERONRED 500 (for example, if you are a health care provider).
- **If you are having sex with a pregnant woman, use a condom to protect the unborn child, during treatment and for 3 months following the last dose of TERONRED 500.**
- **If you are having sex with a woman who can become pregnant, use a condom and another effective birth control method, until 3 months after the last dose of TERONRED 500.**
- **If you are a female sexual partner (who can become pregnant) of a male patient receiving TERONRED 500, you should use highly effective contraception during your partner's treatment and for 6 months after your partner has stopped treatment with TERONRED 500.**
- Men should not father a child while receiving treatment with TERONRED 500. Men should use highly effective contraception while using TERONRED 500 and for at least 3 months after stopping treatment with TERONRED 500.
- Men who might want to father a child should consider storing sperm before treatment, since TERONRED 500 may lower fertility.

Driving and using machines

TERONRED 500 is not likely to affect your being able to drive and use any tools or machines. It is not always possible to predict to what extent TERONRED 500 may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities

until they are aware of the measure to which TERONRED 500 affects them.

TERONRED 500 contains lactose and sodium

TERONRED 500 contains lactose (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 TERONRED 500.

TERONRED 500 contains sodium which is a type of salt. If you are on a controlled salt diet, contact your doctor before taking TERONRED 500.

3. How to take TERONRED 500

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

Always take TERONRED 500 exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will decide on the most suitable treatment for you depending on:

- the correct dose
- how often and for how long you should be treated and whether you should also receive other medicines with TERONRED 500 or not.

Your doctor will give you all the necessary information on your treatment plan.

The usual dose is 1 g (two 500 mg tablets) once a day.

- Take this medicine by mouth.
- Swallow the tablets whole with water.
- Do not break the tablets.
- Do not take TERONRED 500 with food.
- Take TERONRED 500 on an empty stomach, at least one hour before or at least two hours after eating a meal.
- TERONRED 500 is taken with a medicine called prednisone or prednisolone. Take the prednisone or prednisolone exactly as your doctor has told you.

If you have the impression that the effect of TERONRED 500 is too strong or too weak, tell your doctor or pharmacist.

Do not stop treatment early without discussing this with your doctor.

If you take more TERONRED 500 than you should

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

If you forget to take TERONRED 500

- If you forget to take TERONRED 500 or prednisone or prednisolone, take your usual dose the following day. Do not take a double dose to make up for forgotten individual doses.
- If you forget to take TERONRED 500 or prednisone or prednisolone for more than one day, talk to your doctor without delay.

If you stop taking TERONRED 500

- Do not stop taking TERONRED 500 or prednisone or prednisolone unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

TERONRED 500 can have side effects.

Not all side effects reported for TERONRED 500 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TERONRED 500, please consult your health care provider for advice.

If any of the following happens, stop taking TERONRED 500 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, mouth, lips, gums, tongue, throat and neck which may cause difficulty in swallowing or breathing
- throat tightness, shortness of breath and wheezing
- rash, "hives" (raised bumps), blisters or itching.

Allergic reactions, including death, can happen in patients taking TERONRED 500 even after only one dose.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TERONRED 500. 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:

- heart failure (indicated by shortness of breath and extreme exhaustion)
- chest pain (angina pectoris)
- heart beats with an irregular rhythm (atrial fibrillation), rapid heart rate (tachycardia)
- heart attack (myocardial infarction)
- high blood pressure (hypertension, indicated by severe headaches, nausea, blurred vision, fatigue and breathing difficulties)
- swelling due to fluid in your legs or feet (peripheral oedema)
- muscle weakness, muscle twitches or a pounding heart beat (palpitations). These may be signs that the level of potassium in your blood is low (hypokalaemia).
- yellowing of the skin or eyes, darkening of the urine, or severe nausea or vomiting. These may be signs or symptoms of liver problems.

These are all very serious side effects.

You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent:

- severe infections, when chemicals are released into the blood to fight the infection causing inflammation over the entire body (sepsis) usually accompanied by fever and malaise (feeling unwell)
- urinary tract infection (symptoms may include painful urination, bloody or smelly urine)
- low blood potassium (hypokalaemia)
- high fat levels in your blood (hypertriglyceridaemia)
- heart failure, chest pain (angina pectoris), heart beats with an irregular rhythm (atrial fibrillation), rapid heart rate (tachycardia)
- high blood pressure (hypertension)
- runny tummy (diarrhoea), indigestion (dyspepsia)
- liver injury
- liver function test increases
- skin rash
- blood in the urine (haematuria)
- swelling due to fluid in your legs or feet (peripheral oedema)
- bone fractures.

Less frequent:

- adrenal gland problems (related to salt and water problems)
- irregular heartbeats or rhythms (dysrhythmia)
- lung irritation (also called allergic alveolitis)

- liver problems (inflammation of the liver; liver failure)
- muscle pain, muscle weakness (myopathy and rhabdomyolysis).

Side effects with unknown frequencies:

- heart attack (myocardial infarction), changes in ECG - electrocardiogram (QT prolongation)
- non-alcoholic fatty liver disease (NAFLD), cirrhosis (scarring of the liver), liver necrosis (cell death)
- serious allergic reaction.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of TERONRED 500.

5. How to store TERONRED 500

Store at or below 25 ° C.

Keep the containers well closed, protect from light.

This medicine does not require any special storage conditions.

Do not store in a bathroom.

Do not dispose medicines in drains or sewerage systems (e.g. toilets).

Do not use after the expiry date stated on the carton.

Store all medicines out of reach of children.

6. Contents of the pack and other information

What TERONRED 500 contains

The active substance is abiraterone acetate. Each film-coated tablet contains 500 mg abiraterone acetate.

The other ingredients are colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose (silicified) and sodium lauryl sulphate.

The film-coating (Opadry II Purple) contains ferrosoferric oxide / black iron oxide, iron oxide red, macrogol, polyvinyl alcohol, talc and titanium dioxide.

What TERONRED 500 looks like and contents of the pack

TERONRED 500 tablets are purple coloured, oval shaped, biconvex bevel edged film-coated tablets, debossed with "A" on one side and "500" on other side.

TERONRED 500 tablets are available in round, white opaque, high density polyethylene (HDPE) containers in a pack size of 60.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Detailed information on this medicine is available on the Dr. Reddy's Laboratories (Pty) Ltd. website: http://www.drreddys.co.za

For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration:

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