Patient information Leaflet:
Dr. Reddy's Laboratories (Pty) Ltd.
ABIRATERONE DRL 250 (film-coated tablets)

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

ABIRATERONE DRL 250, 250 mg, film-coated tablets

Abiraterone acetate

Contains sugar (lactose monohydrate)

Each film-coated tablet contains 198,65 mg of lactose monohydrate and 6,38 mg of sodium.

Read all of this leaflet carefully before you start taking ABIRATERONE DRL 250

- 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.
- ABIRATERONE DRL 250 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 ABIRATERONE DRL 250 is and what it is used for

ABIRATERONE DRL 250 contains a medicine called abiraterone acetate.

ABIRATERONE DRL 250 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 ABIRATERONE DRL 250

Do not take ABIRATERONE DRL 250

- if you are allergic (hypersensitive) to abiraterone acetate or any of the other ingredients of ABIRATERONE DRL 250 (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 ABIRATERONE DRL 250.
- if you are breastfeeding.
- if you are a woman. ABIRATERONE DRL 250 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 ABIRATERONE DRL 250.

Warnings and precautions

Special care should be taken with ABIRATERONE DRL 250:

Tell your doctor or pharmacist before taking ABIRATERONE DRL 250:

- 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
- if you are on chemotherapy
- if you are on certain types of medication which interact with ABIRATERONE DRL 250.

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 ABIRATERONE DRL 250, 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.

ABIRATERONE DRL 250 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 ABIRATERONE DRL 250 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 ABIRATERONE DRL 250 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

ABIRATERONE DRL 250 may affect your liver, and you may not have any symptoms. When you are taking ABIRATERONE DRL 250, your doctor will check your blood periodically to look for any effects on your liver.

Children and adolescents

ABIRATERONE DRL 250 is not for use in children and adolescents. If ABIRATERONE DRL 250 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 ABIRATERONE DRL 250

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 ABIRATERONE DRL 250 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. 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).

ABIRATERONE DRL 250 with food and drink

- ABIRATERONE DRL 250 must not be taken with food (see section 3, "HOW TO TAKE ABIRATERONE DRL 250").
- Taking ABIRATERONE DRL 250 with food may cause side effects.

Pregnancy, breastfeeding and fertility

ABIRATERONE DRL 250 is not for use in women.

- **ABIRATERONE DRL 250 may cause harm to the unborn child if it is taken by women who are pregnant.**
- If you are pregnant or may be pregnant you should wear gloves if you need to touch or handle ABIRATERONE DRL 250 (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 ABIRATERONE DRL 250.**
- **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 ABIRATERONE DRL 250.**
- **If you are a female sexual partner (who can become pregnant) of a male patient receiving ABIRATERONE DRL 250, you should use highly effective contraception during your partner's treatment and for 6 months after your partner has stopped treatment with ABIRATERONE DRL 250.**
- Men should not father a child while receiving treatment with ABIRATERONE DRL 250.

Men should use highly effective contraception while using ABIRATERONE DRL 250 and for at least 3 months after stopping treatment with ABIRATERONE DRL 250.

- Men who might want to father a child should consider storing sperm before treatment, since ABIRATERONE DRL 250 may lower fertility.

Driving and using machines

ABIRATERONE DRL 250 may affect your ability to drive and use machines. You should not drive or use machines before you know how treatment with ABIRATERONE DRL 250 affects you.

ABIRATERONE DRL 250 contains lactose and sodium

ABIRATERONE DRL 250 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 ABIRATERONE DRL 250.

ABIRATERONE DRL 250 contains 25,52 mg sodium (main component of cooking/table salt) in a four-tablet daily dose. This is equivalent to 1,28 % 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 ABIRATERONE DRL 250

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

Always take ABIRATERONE DRL 250 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 ABIRATERONE DRL 250 or not.

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

The usual dose is 1 g (four tablets) once a day.

- Take this medicine by mouth.
- Swallow the tablets whole with water.
- Do not break the tablets.
- Do not take ABIRATERONE DRL 250 with food.
- Take ABIRATERONE DRL 250 on an empty stomach, at least one hour before or at least two hours after eating a meal.
- ABIRATERONE DRL 250 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 ABIRATERONE DRL 250 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 ABIRATERONE DRL 250 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 ABIRATERONE DRL 250

- If you forget to take ABIRATERONE DRL 250 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 ABIRATERONE DRL 250 or prednisone or prednisolone for more

than one day, talk to your doctor without delay.

If you stop taking ABIRATERONE DRL 250

- Do not stop taking ABIRATERONE DRL 250 or prednisone or prednisolone unless your doctor tells you to.

4. Possible side effects

ABIRATERONE DRL 250 can have side effects.

Not all side effects reported for ABIRATERONE DRL 250 are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking ABIRATERONE DRL 250, please consult your health care provider for advice.

I**f any of the following happens, stop taking ABIRATERONE DRL 250 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 ABIRATERONE DRL 250 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 ABIRATERONE DRL 250. 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)
- kidney failure, caused by breakdown of muscle tissue (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 ABIRATERONE DRL 250.

5. How to store ABIRATERONE DRL 250

Store at or below 25° C.

Keep the containers well closed.

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 ABIRATERONE DRL 250 contains

The active substance is abiraterone acetate. Each film-coated tablet contains 250 mg abiraterone acetate.

The other ingredients are colloidal silicon dioxide, croscarmellose sodium, lactose

monohydrate, magnesium stearate, microcrystalline cellulose, povidone and sodium lauryl sulphate.

The film-coat ingredients are opadry white (hypromellose, macrogol and titanium dioxide).

What ABIRATERONE DRL 250 looks like and contents of the pack

ABIRATERONE DRL 250 tablets are white to off white, oval shaped, film coated tablets, debossed with Dr. Reddy's logo on one side and "358" on other side.

ABIRATERONE DRL 250 tablets are available in high density polyethylene (HDPE) containers along with an oxygen absorbent pillow pouch in a pack size of 120.

Holder of Certificate of Registration

Dr. Reddy's Laboratories (Pty) Ltd

Block B, 204 Rivonia Road

Morningside

Sandton

2057

South Africa

Tel.: +27 11 324 2100

This leaflet was last revised in

28 March 2025

Registration number

50/21.12/0857

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:

Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100