PATIENT INFORMATION LEAFLET

Scheduling status: **S4**

ABIRATERONE CIPLA

(Abiraterone acetate 250 mg tablets)

Contains sugar: Lactose Monohydrate 150 mg per tablet

Read all of this leaflet carefully before you start taking ABIRATERONE CIPLA.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- ABIRATERONE CIPLA 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 CIPLA** is and what it is used for
2. What you need to know before you take **ABIRATERONE CIPLA**
3. How to take **ABIRATERONE CIPLA**
4. Possible side effects
5. How to store **ABIRATERONE CIPLA**
6. Contents of the pack and other information

1. WHAT ABIRATERONE CIPLA IS AND WHAT IT IS USED FOR

ABIRATERONE CIPLA contains an ingredient called abiraterone acetate which decreases the production of male hormones called androgens (e.g. testosterone) which slow down the growth of the cancer tissue in your prostate and elsewhere. ABIRATERONE CIPLA in combination with other medicines, is used to treat your prostate cancer which is in an advanced stage and has already spread to other body tissues.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ABIRATERONE CIPLA

Do not take ABIRATERONE CIPLA if:

- You are hypersensitive to the active ingredient or any of the other ingredients of ABIRATERONE CIPLA (listed in **section 6**).
- You are a woman.
- You are pregnant, trying to get pregnant or may potentially be pregnant.
- You have moderate to severe liver damage.
- You have high blood pressure that is not well controlled.
- You have had a heart attack (myocardial infarction) and/or blood clots in your arterial blood vessels in the past 6 months.
- You have severe or unstable angina (severe chest pain because of your heart vessels being narrowed) not well controlled with treatment.
- You have weak functioning of your left heart pumping system (less than 50 % output) not improving with treatment.
- You have heart rhythm disturbances (e.g. irregular heartbeats, rapid heartbeats).

- You have inflammation of your liver (viral hepatitis).
- You have an uncorrected low blood potassium.
- You are to receive vaccinations with a live attenuated bacterial or viral vaccine.
- You have tuberculosis and/or HIV infection that is not well controlled with appropriate treatment.

Warnings and precautions:

Take special care with ABIRATERONE CIPLA:

- If you have mild liver problems. Your doctor will measure your liver enzymes before and during your treatment with ABIRATERONE CIPLA.
- if you have been told you have high blood pressure, low blood potassium or retention of fluids in your body (can be identified by weight gain or swelling in the feet, ankles or legs). Your doctor will monitor these while you are being treated with ABIRATERONE CIPLA.
- if you have taken a medicine known as ketoconazole in the past for prostate cancer
- If you have stopped taking corticosteroid medicines known as prednisone or prednisolone.
- If you are undergoing a stressful event while taking ABIRATERONE CIPLA in combination with prednisone and prednisolone.
- If you have weakened bones (decreased bone density).
- If you have high blood sugar.
- If you are being treated for cancer with chemotherapy.

- If you have condition called anaemia or experience symptoms such as tiredness, dizziness or shortness of breath.
- If you experience problems engaging in sexual activity while being treated with ABIRATERONE CIPLA.
- If you experience muscle weakness or are taking medicines known to cause muscle weakness.

You must tell your doctor if you have any of the conditions or health problems listed above before taking **ABIRATERONE CIPLA.**

Children (under 18 years of age)

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

Pregnant women and women of childbearing potential:

If you are a woman who is pregnant or planning to become pregnant (including healthcare workers), you need to take safety precautions when handling or working with ABIRATERONE CIPLA**.** Always wear gloves when touching ABIRATERONE CIPLA.

Other medicines and ABIRATERONE CIPLA:

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

The following medicines may decrease the effect of ABIRATERONE CIPLA, you must tell your doctor if you are taking any of them while being treated with ABIRATERONE CIPLA:

- Rifampicin, rifabutin and rifapentin: used for treating tuberculosis (TB).
- Phenytoin and carbamazepine: used in the treatment of seizures (fits).
- Phenobarbital: used for sleeping difficulties.
- St John's wort (*Hypericum perforatum*): herbal medicine for treating depression.
- Spironolactone: used for high blood pressure and heart problems.

Tell your doctor if you are also taking any of the following medicines while being treated with ABIRATERONE CIPLA:

- Propafenone and flecainide (both used for treating irregular heart rates).
- Propranolol (used to treat high blood pressure).
- Haloperidol, risperidone (antipsychotic medicines).
- Pioglitazone (used in the treatment of diabetes or high blood sugar).
- Desipramine, venlafaxine (used for depression).
- Codeine, oxycodone, tramadol (pain medicines).
- Dextromethorphan (a cough medicine).

Taking ABIRATERONE CIPLA with any of these above listed medicines increases the incidence of undesirable effects associated with these other medicines.

ABIRATERONE CIPLA with food, drink and alcohol:

Do not take ABIRATERONE CIPLA with food (see **section 3**).

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare provider for advice before handling ABIRATERONE CIPLA

ABIRATERONE CIPLA is not for use in women.

ABIRATERONE CIPLA may cause harm to the unborn child if taken by pregnant women. Do not take ABIRATERONE CIPLA if you are pregnant or breastfeeding.

Pregnant women or those who may be pregnant must use hand gloves if they need to handle ABIRATERONE CIPLA.

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

Driving and using machines:

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

ABIRATERONE CIPLA contains the sugar, lactose monohydrate:

Talk to your doctor before taking ABIRATERONE CIPLA if you are lactose intolerant or intolerant to some sugars.

3. HOW TO TAKE ABIRATERONE CIPLA:

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

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

The usual dose is 4 tablets, taken as a single dose without food.

ABIRATERONE CIPLA must be taken by mouth.

Do not take ABIRATERONE CIPLA with food.

Take ABIRATERONE CIPLA at least two hours after eating and do not eat anything for at least one hour after taking ABIRATERONE CIPLA (see **section 2.4.**).

Swallow the tablets whole with water.

Do not break the tablets.

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

Your doctor will tell you how long your treatment with ABIRATERONE CIPLA will last. Do not stop treatment early. If you have the impression that the effect of ABIRATERONE CIPLA is too strong or too weak, tell your doctor or pharmacist.

If you take more ABIRATERONE CIPLA than you should:

In the event of overdosage, consult your doctor of pharmacist. If neither is available, contact the nearest hospital or poison control center (see also **section on children under 18 years of age**).

If you forget to take a dose of ABIRATERONE CIPLA:

Do not take a double dose to make up for the forgotten individual doses. If you forget to take either **ABIRATERONE CIPLA** or prednisone or prednisolone on any day, please take your next usual dose the following day.

If you stop taking ABIRATERONE CIPLA:

Do not stop taking ABIRATERONE CIPLA or prednisone or prednisolone unless your doctor tells you to. If you have any further questions on the use of ABIRATERONE CIPLA, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS:

ABIRATERONE CIPLA can have side effects.

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

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

- Allergic reactions such as a rash or itching; swelling of face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing.
- Hepatotoxicity (liver damage or impairment), signs include yellowing of the eyes and skin, abdominal or stomach pain and dark urine.
- Muscle weakness, muscle twitches or a pounding heartbeat (palpitations). These may be signs that the level of potassium in your blood is low.

These are all very serious side effects. 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)
- Heart attack.
- High blood pressure (indicated by severe headaches, nausea, blurred vision, fatigue and breathing difficulties).
- Chest pain.
- Abnormal or irregular heartbeat.
- Any sign of an infection, e.g. urinary tract infection (symptoms may include painful urination, bloody or smelly urine). It is important to note that infections are usually accompanied by fever and malaise.

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:

- Diarrhoea (runny tummy),
- Indigestion,
- Bloody urine,
- Rash,
- Swelling in the legs or feet,
- Bone fracturing,

Less frequent side effects:

- Lung irritation (you may experience dry cough),
- Muscle weakness and/or muscle 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 and to Cipla Medpro (Pty) Ltd: drugsafety@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of ABIRATERONE CIPLA.

5. HOW TO STORE ABIRATERONE CIPLA:

Store all medicines out of reach of children.

Store in the original container at or below 25 °C.

Protect from light

Pregnant women or those who may potentially be pregnant must (including healthcare workers) use protection such as gloves when handling (touching) ABIRATERONE CIPLA (see **sections 2.5** and **section 3**).

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What ABIRATERONE CIPLA contains:

Each tablet contains abiraterone acetate 250 mg as the active ingredient.

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

What ABIRATERONE CIPLA looks like and contents of the pack:

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

ABIRATERONE CIPLA is marketed in pack sizes of 120 tablets per pack, in white, opaque, round HDPE bottles fitted with white PP child resistant closures with a liner.

Holder of certificate of registration

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This leaflet was last revised in:

Date of first authorisation: 09 June 2020

Date of revision of text: TBA

Registration number:

52/21.12/0144

Access to the corresponding professional information:

The corresponding professional information can be found in the packaging of this medicine.