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Patient Information Leaflet

SCHEDULING STATUS: [S4]

ENORTERIB 500 mg (Film-coated tablet)

Abiraterone acetate

(Contains sugar: 245,45 mg lactose monohydrate per tablet)

Read all of this leaflet carefully before you start taking

- 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.
- **ENORTERIB** 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 ENORTERIB is and what it is used for

ENORTERIB contains an ingredient called abiraterone acetate which decreases production of male hormones called androgens (e.g., testosterone) and slows the growth of cancer in your prostate and elsewhere.

ENORTERIB is used in combination with other medicines to treat metastatic (cancer that spread to other parts of the body) advanced prostate cancer.

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2. What you need to know before you take ENORTERIB

Do not take ENORTERIB:

- If you are hypersensitive (allergic) to abiraterone acetate or any of the other ingredients of this medicine (listed in section 6)
- If you are a woman, **ENORTERIB** is used in men only
- If you are pregnant or think that you may be pregnant or are trying to get pregnant (see Pregnancy and breastfeeding)
- If you have moderate or severe liver disease
- If you are taking a medicine called rifampicin that is used for the treatment of tuberculosis (TB)
- If you are taking prednisone/ prednisolone with **ENORTERIB**, you should not be given Ra-223.

Do not take this medicine if any of the above applies to you. If you are unsure, talk to your doctor or pharmacist before taking **ENORTERIB**.

Warnings and precautions

Special care should be taken with **ENORTERIB**. Talk to your doctor or pharmacist before taking **ENORTERIB**:

- if you have been diagnosed with 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 or are being treated with medicines for these conditions.
- if you have an irregular or rapid heart rate or are being treated with medicines for these conditions.
- if you have swelling in the feet, ankles, or legs.

- if you have been diagnosed with liver disease. 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. Failure of the liver to function (called acute liver failure) may occur, which can lead to death.
- about the need to take this medicine with prednisone or prednisolone.
- about possible effects on your bones.
- if you have taken a medicine known as ketoconazole in the past for prostate cancer.
- if you have high or low blood sugar.
- about the need to take this medicine with any other chemotherapy.
- about the occurrence of decrease in red blood cells, reduced sex drive (libido), muscle weakness and/or muscle pain.
- if you take Ra-223 following treatment with **ENORTERIB** and prednisone/prednisolone, you must wait 5 days before starting treatment with Ra-223. **ENORTERIB** must not be given in combination with Ra-223 due to a possible increase in the risk of bone fracture or death.

Children and adolescents

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

Other medicines and ENORTERIB

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

In particular, tell your doctor if you are taking medicines such as:

- Rifampicin (an antibiotic used to treat tuberculosis (TB))

- **ENORTERIB** may increase the effects of a number of medicines including heart medicines such as propafenone and flecainide; the cough medicine dextromethorphan and a variety of other medicines such as desipramine, venlafaxine, haloperidol, risperidone, codeine, oxycodone and tramadol.
- Medicines such as phenytoin, carbamazepine, and phenobarbitone (used for fits) rifabutin (used for TB), or St. John's wort (used for depression) as they will decrease the effect of **ENORTERIB**.
- Ketoconazole (an antifungal medication used in the treatment of fungal infections)
- Metoprolol, propranolol (beta blocker medications used to manage abnormal heart rhythms)
- Propafenone (a medicine used to treat illnesses associated with rapid heartbeat)
- Flecainide (a medicine used to prevent and treat abnormally fast heart rates)
- Tell your doctor if you are taking spironolactone (used for high blood pressure), as spironolactone may cause prostate specific antigen (PSA) levels to increase.

Androgen deprivation treatment may increase the risk of heart rhythm problems. Tell your doctor if you are receiving medicine

- Used to treat heart rhythm problems (e.g., quinidine, procainamide, amiodarone and sotalol)
- Known to increase the risk of heart rhythm problems [e.g., methadone (used for pain relief and part of drug addiction detoxification), moxifloxacin (an antibiotic), antipsychotics (used for serious mental illnesses)].

ENORTERIB with food

Do not take **ENORTERIB** with food. Food significantly increases the absorption of **ENORTERIB** and this may cause serious side effects (see *section 3*).

Pregnancy, breastfeeding and fertility

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ENORTERIB is not for use in women.

ENORTERIB may cause harm to the unborn child if it is taken by women who are pregnant.

Do not take **ENORTERIB** if you are pregnant or breastfeeding.

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 **ENORTERIB**.

If you are having sex with a woman who can become pregnant, use a condom and partners must use another effective contraception.

If you are having sex with a pregnant woman, use a condom to protect the unborn child and pregnant partners should use a female condom.

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

Driving and using machines

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

It is not always possible to predict to what extent **ENORTERIB** may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which **ENORTERIB** affects you.

ENORTERIB contains lactose and sodium:

ENORTERIB contains lactose (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 **ENORTERIB**. This medicine also contains sodium and therefore this should be taken into consideration by patients on a controlled sodium diet.

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3. How to take ENORTERIB

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

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

The usual dose of **ENORTERIB** is 2 tablets, taken as a single daily dose.

Do not take **ENORTERIB** with food.

Take **ENORTERIB** at least 1 hour before eating or at least 2 hours after a meal.

Swallow the tablets whole with water.

Do not chew or crush your tablets.

ENORTERIB is take 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 **ENORTERIB** will last. Do not stop early, because this can cause your symptoms to return.

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

If take more ENORTERIB than you should

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

If you forget to take ENORTERIB

If you forgot to take a dose of **ENORTERIB** and/ or prednisone or prednisolone by only a few hours, take the missed dose as soon as you remember. If it is nearly time for your next dose, skip the missed dose and take **ENORTERIB** and/ or prednisone or prednisolone at the regularly scheduled time.

Do not take a double dose to make up for forgotten individual doses.

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If you stop taking ENORTERIB

Do not stop taking **ENORTERIB** 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

ENORTERIB can have side effects.

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

If any of the following happens, stop taking **ENORTERIB** 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.

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

- Heart failure (indicated by shortness of breath and extreme exhaustion)
- Irregular heartbeats (unusually fast, slow or irregular heartbeat)
- High blood pressure (hypertension, indicated by severe headaches, nausea, blurred vision, fatigue and breathing difficulties)

These are all very serious side effects. If you have them, you may have had a serious reaction to **ENORTERIB**. 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 the following:

- 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.
- Rhabdomyolysis (a breakdown of muscle tissue that releases a damaging protein into the blood)

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:

- Sepsis (a life-threatening complication of an infection)
- Hypokalaemia (low blood potassium levels)
- Hypertriglyceridemia (high cholesterol)
- Heart failure
- Angina pectoris (chest pain or discomfort that keeps coming back due to reduced blood flow to the heart)
- Improper beating of the heart, whether irregular, too fast or too slow)
- Diarrhoea (loose, watery stools that occur more frequently than usual)
- Dyspepsia (upper abdominal discomfort, described as burning sensation, bloating or gassiness, nausea or feeling full too quickly after starting to eat)
- Abnormal liver functions including elevated liver function tests such as ALT, AST and total bilirubin as shown by blood tests
- Rash (temporary outbreak of red, bumpy, scaly or itchy patches of skin, possibly with blisters or welts)

- Haematuria (blood in your urine)
- Peripheral oedema (swelling of your lower legs or hands)
- Fractures (excluding fractures caused by an underlying disease condition rather than an injury)

Less frequent side effects:

- Adrenal insufficiency (a condition in which the adrenal glands don't function properly which may cause you to have symptoms such as darkening of your skin, dizziness when standing up, nausea, tiredness, loss of appetite, sweating, craving salty food and excess urination)
- Allergic alveolitis (a lung disorder resulting from repeated inhalation of organic dust)
- Myopathy (diseases that affect the muscles that connect to your bones (skeletal muscles))

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 healthcare provider. 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 **ENORTERIB**.

5. How to store ENORTERIB

Store all medicines out of reach of children.

Do not store above 30 °C.

Keep tightly closed.

Protect from light.

Return all unused medicine to your pharmacist.

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

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Pregnant women or those who may potentially be pregnant must (including healthcare workers) use protection when handling **ENORTERIB**.

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

6. Contents of the pack and other information

What **ENORTERIB** contains

The active ingredient is abiraterone acetate.

The other ingredients are colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, sodium lauryl sulphate, magnesium stearate, microcrystalline cellulose, povidone K-30 and Opadry II 85F500121.

What ENORTERIB looks like and content of the pack

Brownish pink, oval-shaped, film coated tablets debossed with 'G' one side and '121' on the other side packed as 60 tablets packed in 150 mL HDPE container with CR closure 38 mm with liner

Holder of Certificate of Registration

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