



## PACKAGE LEAFLET

### ABYGA 500 mg Film coated Tablets

Taken by mouth.

- **Active substance:** Each film-coated tablet contains 500 mg abiraterone acetate.
- **Excipients:** Lactose anhydrous (from cow's milk), microcrystalline cellulose, croscarmellose sodium, povidone, sodium lauryl sulfate, colloidal silicon dioxide, magnesium stearate, Opadry 85F200050 purple: polyvinyl alcohol, titanium dioxide, macrogol/PEG MW 3350, talc, black iron oxide, red iron oxide.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects that you may get. See the end of section 4 for how to report side effects.

**Read all of this PACKAGE LEAFLET carefully before you start taking this medicine because it contains important information for you.**

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *While you are taking this medicine, tell your doctor that you use this medicine when you go to a doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher** or a **lower** dose other than recommended to you.*

#### **In this leaflet:**

- 1. What ABYGA is and for what it is used**
- 2. What you need to know before you take ABYGA**
- 3. How to take ABYGA**
- 4. Possible side effects**
- 5. How to store ABYGA**

#### **1. WHAT ABYGA IS AND WHAT IT IS USED FOR**

- ABYGA contains abiraterone acetate as the active ingredient. ABYGA stops your body from making testosterone (it is a steroid hormone from the androgen group and is known as the male sex hormone); this can slow the growth of prostate cancer. ABYGA is used in adult men to treat prostate cancer that has spread to other parts of the body.
- When ABYGA is prescribed for the early stage of disease where it is still responding to hormone therapy, it should be used with a treatment that lowers testosterone (androgen deprivation therapy).
- ABYGA is used in adult men to treat prostate cancer that has spread to other parts of the body; for patients with testicles removed or male sex hormone suppressed and who have not received chemotherapy before, patients whose health condition is not suitable for chemotherapy, and patients who have previously received chemotherapy and have relapsed.



When you take this medicine, your doctor will also prescribe another medicine called prednisone or prednisolone. This is to lower your chances of getting high blood pressure, having too much water in your body (fluid retention), or having reduced levels of a chemical known as potassium in your blood.

- ABYGA is a purple, oval-shaped, biconvex film-coated tablet.
- ABYGA is available in blister packs containing 60 tablets in a cardboard box.

## **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ABYGA**

### **DO NOT TAKE ABYGA in the following situations:**

- If you are allergic (hypersensitive) to abiraterone acetate or any of the excipients of ABYGA.
- If you are a woman, especially if pregnant. ABYGA is for use in male patients only.
- If you have severe liver damage.
- In combination with Ra-223 molecule 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 this medicine.

### **USE ABYGA CAREFULLY in the following situations:**

Talk to your doctor or pharmacist:

- If you have liver disorders
- If you have high blood pressure or heart failure or low levels of the element called potassium in your blood (low potassium can increase the risk of heart rhythm problems)
- If you have any other disorder related to your heart or blood vessels
- If you have an irregular or fast heartbeat
- If you have shortness of breath
- If you have gained weight quickly
- If you have swelling of the feet, ankles or legs
- If you have taken a medicine known as ketoconazole for prostate cancer in the past
- If you need information about taking this medicine with prednisone or prednisolone
- If you need information about the possible effects on your bones
- If you have high blood sugar

Consult your doctor if you have any heart or blood vessel conditions, including heart rhythm problems (arrhythmia), or are being treated with medicines for these conditions.

Consult 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.

Decrease in red blood cells, reduced sex drive (libido), muscle weakness and/or muscle pain may occur.

ABYGA must not be given in combination with Ra-223 (radioactive radium therapy used in nuclear medicine) due to a possible increase in the risk of bone fracture or death.

If you plan to take Ra-223 following treatment with ABYGA and prednisone/prednisolone, you have to wait at least 5 days before starting treatment with Ra-223.



### Blood monitoring

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

### Children and adolescents

This medicine is not for use in children and adolescents. If ABYGA 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.

Please consult your doctor or pharmacist if these warnings were applicable to you, even at any time in the past.

### **Using ABYGA with food and drink**

- ABYGA should not be taken with food (see section 3. “HOW TO TAKE ABYGA”).
- Taking ABYGA with food may cause undesirable effects.

### **Pregnancy**

*Consult your doctor or pharmacist before using this medication.*

### **ABYGA is not a medicine for women.**

- **This medicine may cause harm to the unborn child if it is taken by women who are pregnant.**
- **If you are pregnant or likely to become pregnant and you are going to give ABYGA to another person, you should definitely use gloves to avoid contact with the drug.**
- **If you are having sex with a woman who can become pregnant, use a condom and another effective birth control method.**
- **If you have sexual intercourse with a pregnant woman, use a condom to protect the unborn child.**

*If you notice that your partner is pregnant during your treatment, consult your doctor or pharmacist immediately.*

### **Breast-feeding**

*Consult your doctor or pharmacist before using this medication.*

### **ABYGA is not a medicine for women.**

- **Do not use ABYGA if you are breastfeeding.**

### **Driving and using machines**

ABYGA has no possible influence on the ability to drive or use machines.

### **Important information about some of the ingredients of ABYGA**

ABYGA contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

A daily dose of 2 tablets of this medication contains 23.46 mg of sodium. This should be considered for patients on a controlled sodium diet.



### Concomitant use with other drugs

Consult your doctor or pharmacist before taking any medicine.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is important because ABYGA may increase the effects of a number of medicines including heart medicines, tranquilizers, medications for diabetes, herbal remedies (e.g., St John's Wort) and others. Your doctor may want to adjust the dose of these medicines. Also, some medicines may increase or decrease the effects of ABYGA. This may cause side effects or ABYGA not being as effective as it should be.

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

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

*If you are currently using or have recently used any prescription or non-prescription drugs, please inform your doctor or pharmacist about them.*

### 3. HOW TO TAKE ABYGA

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

#### Instructions for proper use and dose/frequency of administration

The recommended dose of this product is 1000 mg (2 tablets) to be taken once a day.

#### Route and method of administration

- Take this medication through your mouth.
- **Do not take ABYGA with food.** Taking ABYGA with food may result in more absorption of the medicine by the body than needed, which can lead to side effects.
- Take ABYGA tablets once daily on an empty stomach as a single dose. ABYGA should be taken at least two hours after eating, and no food should be eaten for at least one hour after taking ABYGA (see section 2, "Using ABYGA with food and drink").
- Swallow the tablets whole with water.
- Do not break the tablets.
- ABYGA is taken with a medicine called prednisone or prednisolone. Take prednisone or prednisolone exactly as your doctor has told you.
- You need to take prednisone or prednisolone every day while you are taking ABYGA.
- Your dosage for prednisone or prednisolone may need to be changed if you have a medical emergency. Your doctor will tell you whether changes should be made in the amount of prednisone or prednisolone that you have been taking. Do not stop taking prednisone or prednisolone unless your doctor tells you to.

Your doctor may also prescribe other medicines while you are taking ABYGA with prednisone or prednisolone.



## Different age groups

### Use in children

ABYGA is **not** a drug that can be used in children and adolescents. If ABYGA is accidentally swallowed by a child or adolescent, go to the hospital immediately, taking this leaflet with you to show it to the doctor.

### Use in the elderly

No dose adjustment studies have been conducted in elderly patients.

## Special use conditions

### Kidney failure

ABYGA can be used in patients with kidney failure, no dose adjustment is required. Caution is advised in patients with severe kidney failure.

### Liver failure

Your doctor will monitor some blood values of your liver at regular intervals and if there is an excessive increase in these values, ABYGA treatment will be stopped completely or at least until your blood values improve. Caution should be exercised when using ABYGA in patients with moderate liver failure. ABYGA should not be used in patients with severe liver failure.

### High blood pressure

If you have high blood pressure (hypertension), your doctor will not prescribe ABYGA for you without checking your blood pressure values. Whether you have a blood pressure complaint or not, your doctor will want your blood pressure to be measured during ABYGA treatment.

*If you have an impression that the effect of ABYGA is too strong or too weak, talk to your doctor or pharmacist.*

## If you take more ABYGA than you should

*If you take more ABYGA than you should, talk to your doctor or pharmacist or go to a hospital immediately.*

## If you forget to take ABYGA

- If you forget to take ABYGA or prednisone or prednisolone, take your usual dose the following day.
- If you forget to take ABYGA or prednisone or prednisolone for more than one day, talk to your doctor without delay.

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

## If you stop taking ABYGA

Do not stop taking ABYGA 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

Like all medicines, ABYGA can cause side effects, although not everyone gets them.



- Very common : may occur in at least 1 in 10 patients.  
Common : may occur less than 1 in 10 patients, but more than 1 in 100 patients.  
Uncommon : may occur less than 1 in 100 patients, but more than 1 in 1,000 patients.  
Rare : may occur less than 1 in 1,000 patients, but more than 1 in 10,000 patients.  
Very rare : may occur less than 1 in 10,000 patients.  
Not known : cannot be estimated from the available data.

**If any of the following occur, stop using ABYGA and IMMEDIATELY inform your doctor or go to the nearest hospital emergency department:**

- Muscle weakness, muscle twitches or a pounding heart beat (palpitations). These may indicate that your blood has a low level of an element called potassium.
- Severe allergic reactions with difficulty swallowing and breathing, swelling of the face, lips, tongue and throat, or an itchy rash

All these are serious side effects. If you get any of these, it means you have a serious allergy to ABYGA. You may need emergency medical intervention or hospitalization.

**Other side effects:**

**Very common:**

- Swelling in your legs or feet
- Low potassium level in your blood
- Liver function test increases
- High blood pressure
- Urinary tract infection
- Diarrhea

**Common:**

- High fat levels in your blood
- Chest pain
- Irregular heart beat (atrial fibrillation)
- Heart failure
- Rapid heart rate
- Severe infections called sepsis
- Bone fractures
- Indigestion
- Blood in urine
- Skin rash

**Uncommon:**

- Adrenal gland problems (related to salt and water problems)
- Abnormal heart rhythm (arrhythmia)
- Muscle weakness and/or muscle pain.

**Rare:**

- Lung irritation (also called allergic alveolitis)
- Failure of the liver to function (also called acute liver failure)



**Not known:**

- Heart attack
- Changes in ECG - electrocardiogram (QT prolongation)
- Severe allergic reactions with difficulty in swallowing or breathing, swollen face, lips, tongue and throat, or an itchy rash

Bone loss may occur in men treated for prostate cancer. ABYGA in combination with prednisone or prednisolone may increase bone loss.

*If you experience any side effects not mentioned in this leaflet, inform your doctor or pharmacist.*

**Reporting of side effects**

If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

**5. HOW TO STORE ABYGA**

*Keep ABYGA out of the reach and sight of children and in its original package.*

Store at room temperature below 25°C.

**Use it in accordance with the expiry date.**

Do not use ABYGA after the expiry date, which is stated on the outer package and blister packs. The expiry date refers to the last day of the month specified.

If you notice any damage on the product and/or package, do not use ABYGA.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**Marketing Authorization Holder:**

DEVA Holding A.Ş.  
Küçükçekmece – İSTANBUL / TÜRKİYE

**Manufacturing Site:**

DEVA Holding A.Ş.  
Kapaklı – TEKİRDAĞ / TÜRKİYE

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