PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Erleada® 60 mg

Erleada® 240 mg

Film-coated Tablets

Active ingredient

Erleada 60 mg

Each film-coated tablet contains:

Apalutamide 60 mg

Erleada 240 mg

Each film-coated tablet contains:

Apalutamide 240 mg

Inactive ingredients and allergens in the preparation – see section 6 "Further Information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Erleada is indicated in adult men for the treatment of:

- metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT).
- non-metastatic castration-resistant prostate cancer (nm-CRPC).

Therapeutic group:

Androgen receptor inhibitor (ARI).

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient (apalutamide) or to any of the additional ingredients contained in the medicine. For a list of the additional ingredients, see section 6 "Further Information".
- You are a woman. Erleada is not intended for use in women. If you are pregnant or may be pregnant, Erleada may harm the unborn baby or cause a miscarriage (please see "Pregnancy, breastfeeding and fertility" section for further information).

Special warnings regarding use of the medicine

Before treatment with Erleada, tell the doctor about your medical condition, especially if:

- You have a history of heart diseases
- You have high blood pressure

- You have diabetes
- You have abnormal amounts of fat or cholesterol in your blood (dyslipidemia)
- You have a medical history of seizures, brain injury, stroke, cerebrovascular events or brain tumors
- You are pregnant or plan to become pregnant. Treatment with Erleada can affect the unborn baby and cause miscarriage
- You are taking medicines to prevent blood clots (e.g., warfarin, acenocoumarol)
- You have heart or blood vessel-related problems, including heart rhythm problems (arrhythmia)
- You have a female partner who is pregnant or may become pregnant.
  - Males who have a female partner who can become pregnant must use effective birth control during treatment and for an additional 3 months after the last dose of Erleada
  - Males must use a condom during sex with a pregnant woman

Consult the doctor if you have questions regarding contraception.
- You are breastfeeding or plan to breastfeed. It is not known if Erleada passes into breast milk
- You know you are at risk of suffering from bone fractures
- You know you are at risk of suffering from falls, especially in elderly patients

Children and adolescents
There is no information regarding safety and efficacy of use of this preparation in children and adolescents.

Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist.
It may be necessary to change the dosage of Erleada or the dosage of the other medicines that you are taking.
Erleada may interact with many medicines.

Tell your doctor if you are taking the following medicines:
- To lower fat levels in the blood (e.g., gemfibrozil)
- To treat bacterial infections (e.g., moxifloxacin, clarithromycin, rifampin)
- To treat fungal infections (e.g., itraconazole, ketoconazole)
- To treat HIV infection (e.g., ritonavir, efavirenz, darunavir)
- To treat anxiety (e.g., midazolam, diazepam)
- To treat epilepsy (e.g., phenytoin, valproic acid)
- To treat gastro esophageal reflux disease (conditions where there is too much acid in the stomach) (e.g., omeprazole)
- To prevent formation of blood clots (e.g., warfarin, clopidogrel, dabigatran etexilate)
- To treat hay fever and allergies (e.g., fexofenadine)
- Medicines to lower cholesterol level (e.g., statins, such as rosuvastatin, simvastatin)
- To treat heart problems or to lower blood pressure (e.g., digoxin, felodipine)
- To treat heart rhythm problems (e.g., quinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide)
- To treat thyroid problems (e.g., levothyroxine)
- To treat gout (e.g., colchicine)
- To lower blood sugar levels (e.g., repaglinide)
- To treat cancer (e.g., lapatinib, methotrexate)

- To treat pain or opioid addiction (e.g., methadone)
- To treat serious mental illnesses (e.g., haloperidol)

Use of the medicine and food
Erleada can be taken with or without food.

Pregnancy, breastfeeding and fertility
If you are pregnant, think you may be pregnant or are planning a pregnancy, do not use Erleada as the medicine may cause injury to your unborn baby and even potential loss of pregnancy.
It is unknown whether Erleada passes into breast milk. If you are breastfeeding, talk to the doctor or pharmacist before taking the medicine.

Men
If your female partner is of child-bearing age, is pregnant or may become pregnant, use effective birth control during treatment with Erleada and for 3 months after the last dose. Males must use a condom during sex with a pregnant female.
Erleada may impair male fertility, which may affect the ability to become pregnant.
Do not donate sperm during treatment with Erleada or for 3 months after the last dose.

3. HOW SHOULD THE MEDICINE BE USED?

Always use the preparation according to the doctor's instructions.
Check with the doctor or pharmacist if you are unsure about the dosage and treatment regimen of the preparation.
The dosage and treatment regimen will be determined by the doctor only.
Take the recommended dose of Erleada once a day, at the same time each day.
Erleada can be taken with or without food.
Take the tablet whole. Do not break or halve the tablet.
Erleada comes in 2 different strengths (60 mg and 240 mg).
Do not stop taking Erleada before consulting your doctor.
Do not exceed the recommended dose.

During treatment with Erleada, you should start or continue taking a gonadotropin-releasing hormone (GnRH) analog unless you have undergone or are due to undergo surgery to lower the amount of testosterone in your body (surgical castration).

If you have taken a higher dosage than recommended, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or to a hospital emergency room and bring the package of medicine with you.

If you forgot to take the medicine, take the regular dose as soon as possible on the same day. On the following day, return to your normal dosing regimen. Do not take more tablets than usual to make up for a forgotten dose.
Adhere to the treatment as recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Erleada may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Erleada may cause serious side effects, including:

Heart diseases, stroke, or mini-stroke – bleeding in the brain or blockage of the arteries in the heart or in parts of the brain have happened in some patients during treatment with Erleada and may lead to death. The doctor will monitor you for signs and symptoms of heart or brain problems during the treatment with Erleada. Call the doctor or get medical help right away if you suffer from:

- Chest pain or discomfort at rest or with activity
- Shortness of breath
- Numbness or weakness of the face, arms or legs, especially on one side of the body
- Trouble talking or understanding
- Trouble seeing in one or both eyes
- Dizziness, loss of balance or coordination, or trouble walking

Falls and fractures –Erleada treatment can cause bones and muscles to weaken and increases the risk of falls and fractures. Falls and fractures have happened to people being treated with Erleada. Your doctor will assess the risks of falls and fractures during treatment with Erleada.

Seizures –Treatment with Erleada may increase the risk of seizures. You should avoid activities where a sudden loss of consciousness could cause serious harm to yourself or others. Tell your doctor immediately if you experience loss of consciousness or seizures. Your doctor will instruct you to stop taking Erleada if you experienced a seizure during treatment.

Severe skin effects –Treatment with Erleada may cause severe skin effects which may be life-threatening or lead to death. Stop taking Erleada and seek medical help immediately if you develop any of the following signs or symptoms associated with a severe skin reaction:

- Severe rash or a rash that continues to get worse
- Fever or flu-like symptoms
- Swollen lymph nodes
- Blisters or sores in the mouth, throat, nose, eyes or genital area
- Blistering or peeling of the skin

The most common side effects of Erleada include:

- Feeling very tired
- Joint pain
- Rash – tell your doctor if you are suffering from a rash
- Decreased appetite
- Falls
- Weight loss
- High blood pressure
- Hot flashes
- Diarrhea
- Fractures

Additional side effects associated with **metastatic castration-sensitive prostate cancer (mCSPC)**

Body system	***Side effect***
Musculoskeletal and connective tissue	Arthralgia

disorders	
Skin and subcutaneous tissue disorders	Rash Pruritus
Vascular disorders	Hot flashes Hypertension
Abnormality in laboratory test results	White blood cell decreased Hypertriglyceridemia

Additional side effects:

- Diarrhea
- Muscle spasms
- Abnormal or changed sense of taste
- Hypothyroidism

Additional side effects associated with **non-metastatic castration-resistant prostate cancer (nmCRPC)**

Body system	***Side effect***
General disorders and administration site conditions	Fatigue
Musculoskeletal and connective tissue disorder	Arthralgia
Skin and subcutaneous tissue disorders	Rash
Metabolic and nutritional disorders	Decreased appetite Peripheral edema
Injury, poisoning and procedural complications	Falls Fractures
Investigations	Weight decreased
Vascular disorders	Hypertension Hot flush
Gastrointestinal disorders	Diarrhea Nausea
Abnormality in hematological test results	Anemia Abnormal decrease in white blood cell count (leukopenia) Low white blood cell level (lymphocytes) (lymphopenia)
Abnormality in laboratory test results	High blood cholesterol level

	High blood sugar level High level of blood triglycerides High blood potassium level

Additional side effects:
- Hypothyroidism
- Itching
- Heart failure

Additional side effects that have been reported after use:
The following side effects have been observed during use of the medicine after it was approved:
Respiratory, chest and chest cavity disorders: interstitial lung disease
Skin and subcutaneous tissue disorders: Stevens-Johnson syndrome and toxic epidermal necrolysis.
You doctor may reduce the dosage of the medicine, temporarily discontinue treatment with the medicine or tell you to permanently stop treatment if you suffer from certain side effects.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
Do not store Erleada above 25°C.
Erleada comes in a child-resistant bottle.
Store the tablets in the original package to protect from light and moisture.
The bottle contains a desiccant to help keep the preparation dry (protect it from moisture). Do not remove the desiccant from the package.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Erleada 60 mg
Tablet core
Microcrystalline Cellulose, HPMC-AS (Hydroxypropyl Methylcellulose Acetate Succinate), Silicified Microcrystalline Cellulose, Croscarmellose Sodium, Colloidal Anhydrous Silica, Magnesium Stearate.

Tablet coating

Opadry II 85F210036 Green: Polyvinyl Alcohol - Partially Hydrolyzed, Titanium Dioxide, Macrogol/Polyethylene Glycol, Talc, Iron Oxide Yellow, Iron Oxide Black.

Erleada 240 mg
Tablet core
HPMC-AS (Hydroxypropyl Methylcellulose Acetate Succinate), Silicified Microcrystalline Cellulose, Croscarmellose Sodium, Colloidal Anhydrous Silica, Magnesium Stearate.

Tablet coating

Opadry QX 321A275010 Gray: Macrogol Poly (vinyl alcohol) Grafted Copolymer, Talc, Titanium Dioxide, Glycerol Monocaprylocaprate Type I, Poly (vinyl alcohol), Iron Oxide Black.

What the medicine looks like and the contents of the package:
Erleada 60 mg
Erleada 60 mg is a slightly yellowish to grayish-green, rectangular, film-coated tablet with the inscription "AR 60" on one side.
The tablets come in a plastic bottle containing 120 film-coated tablets.

Erleada 240 mg
Erleada 240 mg is a bluish-gray to gray, oval-shaped, film-coated tablet with the inscription "E240" on one side.
The tablets come in a plastic bottle containing 30 film-coated tablets.
Each bottle (60 mg and 240 mg) contains a silica gel desiccant that must be left in the bottle to protect the tablets. The desiccant comes in a separate pouch or container. Do not swallow the pouch/container.

Manufacturer:
Erleada 60 mg: Janssen Biotech, Inc., 800/850 Ridgeview Drive, Horsham, PA 19044, USA
Erleada 240 mg: Catalent Pharma Solutions, LLC, 1100 Enterprise Drive, Winchester, KY 40391, USA

Registration Holder: J-C Health Care Ltd., Kibbutz Shefayim 6099000, Israel.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:
Erleada 60 mg: 162-84-35698-00
Erleada 240 mg: 177-74-37868-99

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