Apalutamide ERLEADA®

Patient information sheet V2, October 2024



WHAT IS ERLEADA® APALUTAMIDE?

- An antihormone therapy drug used to treat some prostate cancers.
- Prescribed by your hospital-based oncologist or cancer specialist at least every 12 months; can be renewed by your registered physician.
- Available from community pharmacies on presentation of your prescription.

Film-coated tablet, two dosages available:

- 60 mg: yellowish to greyish-green oblong tablet, with "AR 60" on one side
- 240 mg: blueish-grey to grey oval tablet, with "E240" on one side
- Do not store above 25°C, and keep out of the sight and reach of children.
 - Do not take the tablets out of the blister pack to put them in a pillbox.
- Wash your hands carefully before and after handling the tablets.
- I Do not throw away opened blister packs or boxes, please return them to your pharmacist.

HOW TO TAKE THIS MEDICINE

When?	i	= 1 dose per day at a set time With or without a meal
How?	Swallow the tablets whole, with water, at the same time every day. Do not chew, cut or crush them.	

If you cannot swallow the tablet, it can be dispersed in still water, then mixed with orange juice, green tea, applesauce, or yoghurt drink (see Patient Leaflet included with your medicine).

You can use your **medical diary*** and a **calendar** to note doses.

Do not stop taking or change how you take your treatment without consulting your doctor. This leaflet is not a prescription, please refer to your most recent prescription.

IF YOU FORGET TO TAKE YOUR MEDICINE OR VOMIT

- If you forget to take your medicine, take the missed dose as soon as possible on the same day.
 Continue your treatment at the usual time and dose the following day (do not take a double dose).
 Keep a record in your medical diary*.
 - If you throw up, do not take another dose. Take your next dose at the usual time, do not take a double dose. Keep a record in your medical diary*.

INTERACTION WITH OTHER MEDICINES AND OTHER INTERACTIONS



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Check with your **doctor or pharmacist** that the medicines (prescribed or over-the-counter), other substances (foods, spices and plants, probiotics, essential oils, food supplements, etc.) and derivative products you use are **compatible with your treatment**. The molecules they contain, their dose and how often they are taken can interact with your treatment and affect effectiveness and the occurrence of side effects.



You and your partner must use effective methods of contraception (condoms and another method) throughout treatment **and for 3 months after the last dose**.

Male fertility can be affected during treatment with apalutamide. Your doctor can tell you more about the possibility of sperm banking before starting treatment.

* Patient diary available (in French) at <u>www.omedit-fiches-cancer.fr</u>

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WHAT SIDE EFFECTS CAN OCCUR WITH ERLEADA® APALUTAMIDE?

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Like all medicines, apalutamide may cause side effects, although not everybody gets them.		
Side effects		Prevention
	Hair loss	Use a wide tooth comb or brush with soft natural bristles. Use a gentle shampoo, rinse your hair with warm water and air dry (or at low temperatures). Avoid blow drying and hair dye, which could damage your hair.
	Rash	Use soap-free gel or a dermatological bar. Avoid hot water. Pat dry. Use moisturiser (cream or milk). Avoid sun exposure, particularly between noon and 4pm. Wear protective clothing, even under a parasol (UVA reflection). Use SPF 50+ sun cream, applied 30 minutes before exposure and reapplied every 2 hours.
	Itching	Apply cold compresses to the affected areas (do not use alcohol-based lotions). Wear loose, light cotton clothing. Use soap-free gel or a dermatological bar. Avoid hot water. Pat dry. Use moisturiser (cream or milk). Keep your nails short (use a nail file rather than clippers).
- Fr	Diarrhoea	Monitor your weight. Drink sweet and/or salty beverages: water, tea with sugar, soda, soups. Avoid water containing magnesium (CONTREX [®] , HEPAR [®]), coffee, iced drinks. Eat foods low in fibre (carbohydrates, carrots, bananas); avoid food that can stimulate digestion (dairy products, raw fruit/vegetables, grains, fatty foods, spices). Wash your hands regularly. Contact your doctor if you also have fever or if symptoms continue for more than 5 days.
- Al	Joint pain	Exercise regularly (suitable activities include walking and swimming). Use a walking stick to support your joints. Avoid repetitive movements and strenuous physical effort.
	Hot flashes	Cool down with a mister; remember to hydrate. Wear cotton clothing, do not cover up too much. Avoid triggers (cigarettes, alcohol, hot or spicy food, stress).
	High blood pressure	Headaches, dizziness, and tinnitus are the first warning signs of high blood pressure. Measure your blood pressure (resting and sitting down, in the morning before breakfast and in the evening before going to bed; take three measurements two minutes apart); keep a record of your results. Exercise regularly (suitable activities) (30 minutes 3 times per week). Limit salt (max. 5 g per day) and alcohol. Eat a diet low in saturated fats (animal fats) and high in fibre.
P	Elevated cholesterol levels	Limit saturated fatty acids (e.g. cheese, cream, butter, fatty meat, cold meats). Eat more white fish, grains, carbohydrates, dairy products, fruit and vegetables. Steam, bake, boil or grill food. Exercise regularly.
SSS I III	Tiredness	Eat a balanced diet. Avoid using psychostimulants (e.g. coffee, tobacco, alcohol). Take care when driving. Rest during the day, while maintaining up to moderate levels of activity. Go to bed at a regular time and get sufficient sleep at night.
-`@	Only the most common side effects are listed here. For more information, read the Patient Leaflet included with your medicine or ask your doctor or pharmacist. You can also ask your <u>Regional Pharmacovigilance Centre</u> and report any side effects online: <u>signalement-sante-gouv-fr</u>	



Remember to go for the lab tests prescribed by your doctor.

WHAT TO DO IF YOU EXPERIENCE SIDE EFFECTS

- Take the medicine prescribed to counteract the side effects, as prescribed.
- Follow the preventive measures.

Contact your doctor rapidly in case of:

- Palpitations, malaise, dizziness, difficulty breathing or chest pain.
- Reddish patches on your skin or mucous membranes
- Muscle weakness or paralysis affecting part of your body
- Any persistent or worsening side effect



Useful contacts:

Note: