



Provincial Health Services Authority

For the Patient: UGUPAPA

Treatment of Non-Metastatic Castration Resistant Prostate Cancer Using Apalutamide

U = Undesignated (requires Compassionate Access Program (CAP) approval)

GU = GenitoUrinary

P = Prostate

APA = APAlutamide

ABOUT THIS MEDICATION

What is this drug used for?

- Apalutamide (ERLEADA®) is used to treat prostate cancer that has not spread to other parts of the body and does not respond to other hormonal therapy.

How does this drug work?

- Apalutamide is an oral medication that blocks the effects of testosterone and reduces tumor size.

TREATMENT SUMMARY

How is this drug given?

- Apalutamide is given as a tablet by mouth.
- The starting dose is 240 mg by mouth once daily. A cycle of this medication is 4 weeks and you will go through multiple cycles depending on your response to treatment and/or side effects experienced.
- Doses may be reduced depending on side effects experienced.
- Apalutamide can be taken with food or on an empty stomach.
- If you miss a dose, take it as soon as you can if it is within 12 hours of the missed dose. If it is more than 12 hours since your missed dose, skip the missed dose and go back to your usual dosing times. Do not double the dose.

What will happen when I get my drugs?

- Blood tests and blood pressure measurements may be taken regularly during treatment. The dose of your medication may be changed based on your blood tests and/or other side effects.
- It is recommended that you monitor your blood pressure regularly and keep a journal to give to your physician.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Your doctor will review the risks of treatment and possible side effects with you before starting treatment.

Side effects for **APALUTAMIDE** are listed in the following table in the order in which they may occur. Tips to help manage the side effects are included.

SIDE EFFECTS	MANAGEMENT
Nausea and vomiting may occur with apalutamide. Most people have little or no nausea.	To help nausea: <ul style="list-style-type: none">• Drink plenty of fluids.• Eat and drink often in small amounts.
Skin rashes may sometimes occur.	If itching is very irritating, call your doctor. Otherwise, be sure to mention it at your next visit.
Diarrhea may sometimes occur.	If diarrhea is a problem: <ul style="list-style-type: none">• Drink plenty of fluids.• Eat and drink often in small amounts.• Avoid high fibre foods
Constipation may sometimes occur.	<ul style="list-style-type: none">• Exercise if you can.• Gradually increase fiber intake daily and drink plenty of fluids
Headache may sometimes occur.	Take acetaminophen (e.g., TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day.
Muscle or joint pain may sometimes occur.	You may take acetaminophen (e.g., TYLENOL®) every 4-6 hours to a maximum of 4 g (4000 mg) per day or ibuprofen (e.g., ADVIL®) for mild to moderate pain. Tell your doctor if the pain interferes with your activity.
Swelling of hands, feet, or lower legs may sometimes occur if your body retains extra fluid.	If swelling is a problem: <ul style="list-style-type: none">• Elevate your feet when sitting.• Avoid tight clothing.

SIDE EFFECTS	MANAGEMENT
<p>Hot flashes (sudden sweating and feelings of warmth) sometimes occur with apalutamide.</p>	<p>If hot flashes are troublesome:</p> <ul style="list-style-type: none"> • Take your apalutamide at bedtime. • If night sweats interfere with sleep, try taking apalutamide in the morning. • Some people find it helpful to avoid alcohol, spicy food, and caffeine (coffee, tea, colas, chocolate). • Follow a regular exercise program. • Try staying in a cool environment. • Wear layers so that if you do experience a hot flash, the outer layers may be removed. • Ask your doctor for more advice if your hot flashes continue to bother you. There may be medications available.
<p>Sugar control may commonly be affected in diabetic patients.</p>	<p>Check your blood sugar regularly if you are diabetic.</p>
<p>You may sometimes have trouble sleeping.</p>	<ul style="list-style-type: none"> • Talk to your doctor if you continue to have trouble sleeping. • This will return to normal when you stop taking apalutamide.
<p>Taste alteration may sometimes occur.</p>	<p>Speak to your doctor if this occurs.</p>
<p>Loss of appetite and weight loss sometimes occur.</p>	<ul style="list-style-type: none"> • Increase high calorie/protein fluids such as full-fat milk, homemade smoothies, nutritional supplements • Limit fluid intake prior to meals • Increase intake of high calorie foods
<p>High blood pressure may sometimes occur.</p>	<p>Your blood pressure will be checked during your visits to your doctor.</p> <ul style="list-style-type: none"> • You may be asked to check your blood pressure frequently between visits. • Your doctor may give you medication if your blood pressure is high. • Tell your doctor if you are already on blood pressure medication. Your doctor may have to adjust your dose.
<p>Tiredness and lack of energy may sometimes occur.</p>	<ul style="list-style-type: none"> • Do not drive a car or operate machinery if you are feeling tired.

SIDE EFFECTS	MANAGEMENT
<p>Increase in cholesterol or triglycerides. (one of the types of fat in the blood) commonly occurs.</p>	<p>Discuss this with your doctor if you have:</p> <ul style="list-style-type: none"> • A history of heart disease. • High blood pressure. • High cholesterol or triglycerides. <p>You may need to have your cholesterol level checked a few months after starting apalutamide.</p>

INSTRUCTIONS FOR THE PATIENT:

SEE YOUR DOCTOR OR GET EMERGENCY HELP IMMEDIATELY IF YOU HAVE:

- **Seizures** or **loss of consciousness**.
- Signs of **heart or lung problems** such as fast or uneven heartbeat, chest pain, chest pressure, shortness of breath or difficulty breathing, swelling of feet or lower legs, or fainting.

SEE YOUR DOCTOR AS SOON AS POSSIBLE (DURING OFFICE HOURS) IF YOU HAVE:

- Signs of **anemia** such as unusual tiredness or weakness.
- Signs of **bladder problems** such as changes in urination, painful burning sensation, presence of blood, or abdominal pain.

If you experience symptoms or changes in your body that have not been described above but worry you, or if any symptoms are severe, contact _____ at telephone number _____