

Apalutamide

Erleada®

Hormonal therapy in tablets

Understanding your treatment

What is a hormonal therapy?

Hormonal therapy slows the growth of cancers that use natural hormones (for example: estrogen, progesterone and testosterone) to grow. Hormonal therapy can either stop the body from producing the hormones that cause cancer growth or it may prevent the use of the hormones by the cancer cells.

Hormonal therapy can be used alone or in combination with other treatments such as a targeted therapy.

How can hormonal therapy help you?

Depending on your type of cancer and the stage of the disease, hormonal therapy can be used to :

- **Destroy** cancer cells
- **Stop** the cancer from spreading
- **Slow** the growth of cancer cells

How will you feel while on hormonal therapy?

Hormonal therapy changes the hormone levels in your body. Side effects that are caused by the decrease of hormones can arise at any time during your treatment.

Not everyone has side effects and each person's experience may be different. Side effects and their severity are not representative of hormonal therapy's effectiveness or lack thereof.

This document is about the most frequent side effects caused by your hormonal therapy.

Medication

Apalutamide

Tablets to take by mouth

Administration

To be taken once a day

To be taken with or without food

On a continuous basis



A **blood test** will be done throughout your treatment. Depending on the results and side effects of the previous treatment, the dose of the medication might be adjusted or the treatment might be stopped if necessary.

How to take your medication ?

- Take your apalutamide tablets, as prescribed once a day, at the same time everyday. You may take your pills with or without food with a large glass of water or juice. If you have difficulty tolerating it, for example, if it causes a stomach ache, take it while you eat.
- Tablets must be taken whole. Do not chew, split or crush the tablets.
- **If you forget a dose**, you may take it as soon as you remember but do not double your next dose. Try, however, to take your pills at the same time every day and in the same way (either with or without food).

Storing and handling your medicines



- Wash your hands immediately after handling your tablets.
- Keep your medication at room temperature, out of the reach of children and pets as well as protected from light, heat or moisture. Do not keep medicines in the bathroom.
- Don't throw away unused medication at home. Bring it back to your pharmacy to be destroyed safely. You may dispose of the empty containers in your home garbage can.
- Women who are pregnant or trying to get pregnant should not touch apalutamide tablets. If any of these people help you, they should wear disposable gloves if they prepare medication for you. You can find disposable gloves at your local community pharmacy.
- Keep your medications in their original container and do not mix them with other drugs. The container should never be reused to put other objects or food.

How can this treatment affect your daily life?

Appetite

- Your **appetite may diminish**. Eat more often, in smaller quantities.
- **Alcohol** in small quantities is **allowed** and will not affect the efficacy of the treatments.

Sex life and birth control



- You can have an **active sexual** life during your treatments. However, a decrease in your sexual drive may occur during this period. This may also be influenced by different factors (fatigue, stress, etc.).
- It's safe to kiss, to touch, to hold hands, to sleep in the same bed and to cuddle.
- For **male patients**, the production of spermatozoids may be reduced or completely absent during treatments. This reduction of fertility may be permanent, may get better or return to normal after the treatments have stopped. This reduction of **fertility** does

not prevent erection or sexual activity and a pregnancy remains possible.

- The treatment may affect the sperm and it may be harmful to the embryo.
 - If you have sex with a woman of child-bearing age, a birth control method is strongly recommended during treatments and up to 3 months after the end of treatment.
 - Notify your doctor immediately if you had unprotected sex and your partner is pregnant.

Tips and precautions



- **Over the counter medicines, natural health products and vaccines**

Consult your healthcare team:

- if you intend to take any other medication (with or without a prescription) or natural health products.
- if you need to receive a vaccine.

This could decrease your treatment's efficacy or increase its side effects.

- **Always have on hand the complete list of your medications**

Be sure to always have on hand the complete list of your medications, dietary supplements, vitamins and other natural health products. Give it to your doctor and your pharmacist. It is important to make them aware of any change.



What are the side effects of your treatment?

This fact sheet aims to let you know the side effects most commonly seen following the administration of your treatment. Please note that when you take any medication, there is a possibility that it causes rare side effects and it is difficult to predict which patients will be affected.

ADVERSE EFFECTS

MANAGEMENT

Fatigue

You may experience fatigue during your treatments. This is usually temporary and may be related to different reasons (medication, stress, the disease).

- Maintain a good level of activity but rest when you feel the need to.

High blood pressure

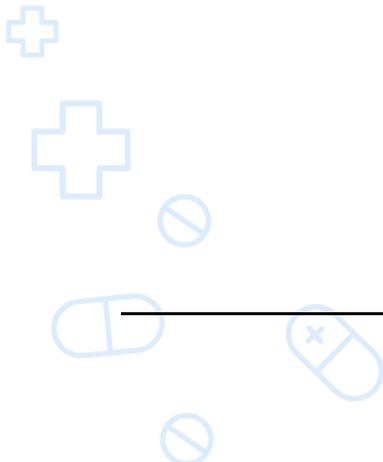
High blood pressure might occur.

- Your blood pressure might be checked during your visit with your doctor.
- A member of your healthcare team might ask you to measure your blood pressure regularly and record it in a diary.
- If you experience high blood pressure, medication can be prescribed to control it.
- ✔ **Continue your treatment if:** your resting blood pressure is below 140/90 mmHg.
- ⚠ **Continue your treatment and call your healthcare team as soon as possible if:** your blood pressure is above 140/90 mmHg over a short period of time or less than 24 hours.
- ✖ **Stop your treatment and call your healthcare team as quickly as possible if:** your blood pressure is above 160/100 mmHg all or most of the time over a period of 24 hours. **Head to the Emergency Room** if your blood pressure is above 200/120 mmHg or if you have a headache or are confused.

Skin problems

A skin rash, usually mild, may occur during your treatment. It may be associated with itchiness.

- ✔ **Continue your treatment but contact your healthcare team if:** you develop skin problems such as pimples or redness, scattered on your skin but that are **not** itchy or tender.
- ⚠ **Continue your treatment and contact your healthcare team as soon as possible if:** you develop skin problems such as pimples or redness, scattered on your skin and they itch or are tender.
- ✖ **Stop your treatment and contact your healthcare team without delay or head to the Emergency Room:** if you develop skin problems, such as pimples or redness all over your body with heat, pain or swelling.



ADVERSE EFFECTS

MANAGEMENT

Diarrhea

You may sometimes experience diarrhea.

- Drink lots of liquids (8 to 10 glasses a day) unless otherwise instructed by your doctor.
- Eat and drink often but in small quantities.
- ✔ **Continue your treatment if:** you have light diarrhea (2 to 3 additional loose stools per day compared to usual before starting your treatment). Start loperamide (Imodium®) by taking 2 tablets first followed by one tablet after each loose stool for a maximum of 8 tablets per 24 hours period. Contact a member of your healthcare team if the diarrhea does not improve after taking loperamide for 24 hours.
- ⚠ **Continue your treatment and call your healthcare team as soon as possible if:** you experience more than 4 to 6 additional loose stools per day compared to usual before starting your treatment). Start loperamide (Imodium®) by taking 2 tablets first followed by one tablet after each loose stool for a maximum of 8 tablets per 24 hours period.
- ✖ **Stop your treatment and call your healthcare team as quickly as possible or go to the Emergency Room if:** you have 7 or more additional loose stools per day compared to usual before starting your treatment, if you are not able to hold it in (incontinence) or if you have diarrhea with a fever.

Hot flashes

You may experience hot flashes. These effects vary between individuals and usually go away with time.

- Take your medication at bedtime.
- However, if the hot flashes disturb your sleep, take your medication in the morning.
- If these symptoms persist over time or are bothering you, speak with your healthcare team that will recommend appropriate measures.

Nausea

Rarely, slight nausea may occur during your treatment.

- Contact a member of your healthcare team if you have nausea that bothers you.

Hair loss

Usually there is **no hair loss** with this treatment.



RARE ADVERSE EFFECTS THAT CAN BE SEVERE OR SERIOUS

If the following side effects occur, stop your treatment and call your healthcare team as quickly as possible or go to the Emergency Room:

- Seizures or fainting

PHARMACIST : _____

PHONE : _____

FROM ___ H___ TO ___ H___ (MONDAY TO FRIDAY)

This fact sheet has been prepared by a sub-committee of the Comité national de l'évolution de la pratique des soins pharmaceutiques of the Programme québécois de cancérologie of the Ministry of Health and Social Services in consultation with the Comité de l'évolution de la pratique en oncologie of the Institut national d'excellence en santé et en services sociaux.

DEVELOPED FEBRUARY 2020



Treatment Diary | Apalutamide 30 days

CYCLE START DATE :

LEGEND

-  Continue your treatment.
-  Continue your treatment and contact your healthcare team as soon as possible.
-  Stop your treatment and contact your healthcare team without delay or go to the Emergency Room.

Refer to the information sheet for more details.

CYCLE DAYS

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30

(Record the dose taken)

mg

Date (dd-mm)

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
HIGH BLOOD PRESSURE																														
 Resting blood pressure below 140/90 mmHg.																														
 Blood pressure above 140/90 mmHg over a short period of time or less than 24 hours.																														
 Blood pressure above 160/100 mmHg all or most of the time over a period of 24 hours.																														
SKIN PROBLEMS																														
 Skin problems that you did not have before such as pimples or redness, scattered on your skin but that are not itchy or tender.																														
 Skin problems that you did not have before such as pimples or redness, scattered on your skin and they itch or are tender.																														
 Skin problems that you did not have before such as pimples or redness all over your body with heat, pain or swelling.																														

DIARRHEA	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
 Light diarrhea: you have 2 to 3 additional loose stools per day compared to usual.																														
 Moderate diarrhea: you have 4 to 6 additional loose stools per day compared to usual.																														
 Severe diarrhea: you have 7 or more additional loose stools per day compared to usual before starting your treatment or you are not able to hold it in (incontinence).																														