PLUVICTO™
lutetium (^{177}Lu) vipivotide tetraxetan injection

Not an actual patient

Your guide to **PLUVICTO™**

This guide provides helpful information about PLUVICTO™ and your treatment journey.

PLUVICTO™ is used to treat adults with a certain type of advanced prostate cancer (called prostate-specific membrane antigen-positive metastatic castration-resistant prostate cancer [PSMA-positive mCRPC]) that is metastatic (this means it has spread to other parts of the body) and that has already been treated with other anti-cancer treatments.

My PLUVICTO™ Drug Identification Number (DIN): 02530198

For more PLUVICTO™ information and resources visit pluvicto.ca:

Dear Patient,

You and your healthcare team have decided to initiate PLUVICTO™ therapy to treat your prostate-specific membrane antigen-positive metastatic castration-resistant prostate cancer (PSMA-positive mCRPC) that has already been treated with other anti-cancer treatments.

This patient brochure will provide you with information on PLUVICTO™ as well as helpful tips to guide you along the way before, during and after administration.

If you have questions that are not answered by this brochure, please do not hesitate to consult your healthcare team again, for additional support.

Your guide to PLUVICTO™

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What is PLUVICTO™ used for?

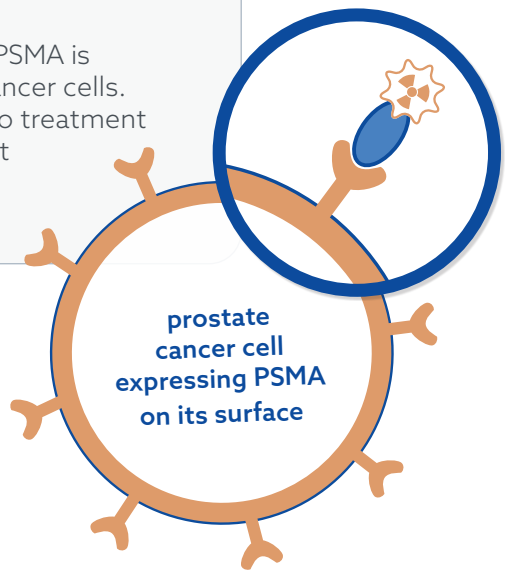
PLUVICTO™ is a radiopharmaceutical medicine used to treat adults with a certain type of advanced prostate cancer called PSMA-positive mCRPC that has already been treated with other anti-cancer treatments.

How does PLUVICTO™ work?

PLUVICTO™ binds to a protein called PSMA that is found on the surface of prostate cancer cells.

Once bound, the radiation emitted from the lutetium-177 causes the prostate cancer cells to die.

Tests will be performed to see if PSMA is present on the surface of your cancer cells. Your cancer is likely to respond to treatment with PLUVICTO™ if the test result is positive.



PLUVICTO™ and radioactivity

The use of PLUVICTO™ involves exposure to amounts of radioactivity. Your healthcare team has considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical outweighs the risk due to radiation.

Have questions?

If you have any questions about how PLUVICTO™ works or why this medicine has been prescribed for you, ask your oncologist or nuclear medicine doctor.

Talking to your oncologist

To help avoid side effects and ensure proper use, talk to your oncologist before you take PLUVICTO™. Talk about any health conditions or problems you may have, including if you:

- Have low level of blood cell counts (hemoglobin, white blood cell count, absolute neutrophil count, platelet count);
- Have or have had tiredness, weakness, pale skin, shortness of breath, bleeding or bruising more easily than normal or difficulty to stop bleeding, or frequent infections with signs such as fever, chills, sore throat or mouth ulcers (possible signs of myelosuppression);
- Have or have had kidney problems such as passing urine less often than usual or passing much smaller amounts of urine than usual;
- Have or have had any other type of cancer or treatment for cancer, as PLUVICTO™ contributes to your overall long-term cumulative radiation exposure;
- Are under 18 years of age;
- Are sexually active as all radiopharmaceuticals, including PLUVICTO™, have the potential to cause harm to an unborn baby. PLUVICTO™ may cause temporary or permanent infertility.

Serious Warnings and Precautions

- PLUVICTO™ should be used by health professionals who are appropriately trained in use of radiopharmaceuticals
- Bone marrow suppression that may be severe, life-threatening or that may lead to death. Tell your healthcare provider right away if you get any of the following signs and symptoms at any time during treatment:
  - Tiredness, weakness, and pale skin
  - Shortness of breath
  - Bleeding or bruising more easily than normal or difficulty to stop bleeding
  - Frequent infections with signs such as fever, chills, sore throat or mouth ulcers
  - Kidney impairment can occur in patients treated with PLUVICTO™. Tell your physician about any kidney condition prior to receiving PLUVICTO™

Other warnings you should know about

PLUVICTO™ contains sodium. This medicine contains up to 88.75 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 4.4% of the recommended maximum daily dietary intake of sodium for an adult.

Do not use PLUVICTO™ if you are allergic to lutetium (^{177}Lu) vipivotide tetraxetan or to any of the other ingredients in this medicine.

The ingredients in PLUVICTO™ are:

- Medicinal ingredient: lutetium (^{177}Lu) vipivotide tetraxetan
- Non-medicinal ingredients: acetic acid, gentisic acid, pentetic acid, sodium acetate, sodium ascorbate, water for injections

Taking PLUVICTO™: Before and during treatment

Before treatment | During | After

Before treatment

Arrival & checkup

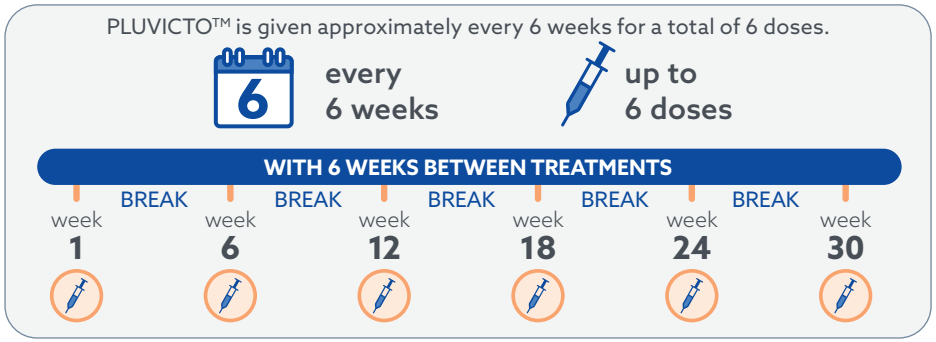
Tell your oncologist about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Your oncologist will do blood tests before and during treatment to check your condition and to detect any side effects as early as possible. Based on the results, your oncologist may decide to delay, modify or stop your treatment with PLUVICTO™ if necessary.

Blood tests before and during treatment

During treatment with PLUVICTO™

Before | **During treatment** | After



PLUVICTO™ is given directly into your vein every 6 weeks for up to a total of 6 doses.

- PLUVICTO™ will be administered intravenously (into your vein) under the supervision of a health professional who is experienced in the use of radiopharmaceuticals
- The recommended dose is 7.4 GBq (gigabecquerel, the unit used to express radioactivity)

Your oncologist or your nuclear medicine doctor will inform you about the usual duration of the procedure.*

Have questions?

If you have questions about how long you will receive PLUVICTO™, talk to your oncologist or your nuclear medicine doctor.

* Your PLUVICTO™ dose is ordered just for you. It is important that you show up for your treatments. Let your oncologist or your nuclear medicine doctor know as early as possible if you have a reason to reschedule the treatment.

Taking PLUVICTO™ – After treatment

Before | During | **After treatment**

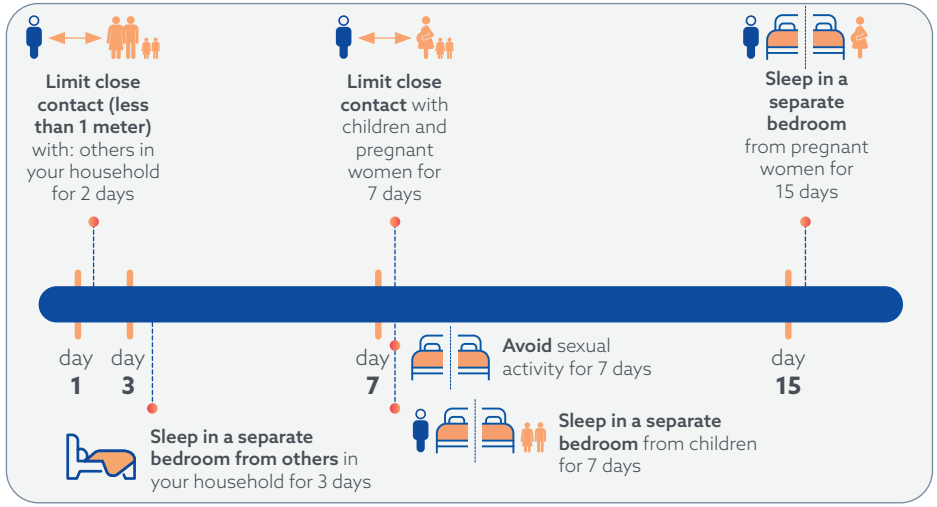
Stay hydrated and urinate frequently

You should drink plenty of water in order to remain hydrated and to urinate as often as possible during the first hours...

....and for 2 days after the administration of PLUVICTO™ to remove the radiopharmaceutical product from your body.

Because this medicine is radioactive, you will have to follow the instructions described below to minimize radiation exposure to others unless otherwise instructed by your nuclear medicine doctor.

Contact with others in your household, children, and/or pregnant women



Use effective birth control throughout treatment with PLUVICTO™ and for 14 weeks after your last dose.

Taking PLUVICTO™ – After treatment (continued)

Use of toilets

Take special precautions to avoid contamination during the 2 days after treatment with PLUVICTO™

- You must always sit when using the toilet.
- It is essential that you use toilet paper every time you use the toilet.
- Always wash your hands well after using the toilet.
- Flush all wipes and/or toilet paper down the toilet immediately after use.
- Flush any tissues or any other items that contain bodily waste, such as blood, urine and feces down the toilet. Items that cannot be flushed down the toilet, such as bandages, must be placed in separate plastic waste disposal bags (according to "Waste disposal recommendations" on the next page).

Showering and laundry

Take a shower every day for at least the first 7 days after treatment. Wash your underwear, pajamas, sheets and any clothes that contain sweat, blood or urine separately from the laundry of others in your household, using a standard washing cycle. You do not need to use bleach and do not need extra rinses.

Hospitalization and emergency care

If for any reason you require emergency medical assistance or are unexpectedly admitted to the hospital during the first week after your treatment, you should inform the healthcare professionals about the nature, date and dose of your radioactive treatment.

People with reduced mobility

People who are confined to bed or have reduced mobility will preferably receive assistance from a care provider. It is recommended that when providing assistance in the bathroom, the care provider wears disposable gloves for 2-3 days after administration. Any special medical equipment that could be contaminated by your bodily fluids (e.g. catheters, colostomy bags, bedpans, water nozzles) must be emptied immediately into the toilet and then cleaned. Carers who clean up vomit, blood, urine or feces should wear plastic gloves, which should be disposed of in a separate plastic waste disposal bag (see "Waste disposal recommendations" below).

Waste disposal recommendations

All items to be thrown away should be discarded in a separate plastic waste disposal bag to be used only for this purpose. Keep the plastic waste disposal bags separate from the other household waste and away from children and animals. A member of the hospital staff will tell you how and when to get rid of these waste disposal bags.

Safety information

Overdose:

An overdose is unlikely. However, in the event of an overdose, you will receive the appropriate treatment. Should you have any further questions on the use of PLUVICTO™, please ask the nuclear medicine doctor who supervises the procedure.

Possible side effects

These are not all the possible side effects you may have when taking PLUVICTO™. If you experience any side effects not listed here, tell your healthcare professional.

Very common: *may affect more than 1 in 10 people*

- Tiredness (*fatigue*)
- Dry mouth
- Nausea
- Loss of appetite
- Changes in bowel movements (*constipation or diarrhea*)
- Vomiting
- Urinary tract infection
- Abdominal pain
- Weight loss

Common: *may affect up to 1 in every 10 people*

- Swollen hands, ankles or feet (*peripheral edema*)
- Dizziness
- Headache
- Disturbed sense of taste (*dysgeusia*)
- Fever (*pyrexia*)
- Dry eye
- Vertigo

Safety information

Serious side effects

If you experience any of the following side effects, talk to your healthcare professional in all cases

VERY COMMON

- Tiredness, weakness, pale skin or shortness of breath (possible signs of low level of red blood cells) (*anemia*)
- Bleeding or bruising more easily than normal or difficulty to stop bleeding and frequent infections with signs such as fever, chills, sore throat or mouth ulcers (possible signs of low level of white blood cells) (*thrombocytopenia, leukopenia, lymphopenia*)

COMMON

- Passing urine less often than usual or passing much smaller amounts of urine than usual (possible sign of kidney problems) (*acute kidney injury*)
- Tiredness, weakness, pale skin, shortness of breath, bleeding or bruising more easily than normal or difficulty to stop bleeding and frequent infections with signs such as fever, chills, sore throat or mouth ulcers (possible signs of low level of blood cells) (*pancytopenia, bone marrow failure, febrile neutropenia*)

UNCOMMON

- Fast or irregular heart beat (*ventricular tachycardia*)
- Bleeding in and/or around the brain that may cause headache, drowsiness, loss of consciousness, confusion, disturbances of speech, movement or sensation (*intracranial hemorrhage, cerebral hemorrhage, subdural hematoma*)
- Liver problems that may cause tiredness, yellowing of the skin and/or eyes known as jaundice, stomach pain (*acute hepatic failure, hepatic failure, hepatocellular injury, cholestasis*)
- Difficulty breathing, low oxygen levels (*acute respiratory failure*)

Although uncommon, if you experience general swelling (generalized edema) talk to your healthcare professional only if it is severe.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Notes for my next appointment

For more PLUVICTO™ information and resources visit pluvicto.ca

PLUVICTO™ is manufactured by Advanced Accelerator Applications USA, Inc. and is imported and distributed by Quality & Compliance Services Inc for Advanced Accelerator Applications Canada, Inc., a Novartis Company.

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MEMBER OF INNOVATIVE MEDICINES CANADA

REVIEWED BY PAAB