PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PLUVICTO™

lutetium (^{177}Lu) vipivotide tetraxetan injection

Read this carefully before you start taking **PLUVICTO™** and each time you receive a dose. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PLUVICTO**.

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 anytime 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.

What is PLUVICTO used for?

This medicine is a radiopharmaceutical product 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.

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 the cancer cells. Your cancer is likely to respond to treatment with PLUVICTO if the test result is positive.

The use of PLUVICTO involves exposure to amounts of radioactivity. Your doctor and the nuclear medicine doctor have considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical outweighs the risk due to radiation.

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

What are the ingredients in PLUVICTO?

Medicinal ingredient: lutetium (^{177}Lu) vipivotide tetraxetan.

Non-medicinal ingredients: acetic acid, gentisic acid, pentetic acid, sodium acetate, sodium ascorbate, water for injections (see Other warnings you should know about "PLUVICTO contains sodium").

PLUVICTO comes in the following dosage forms:

Solution for intravenous injection/infusion, 1000 MBq/mL (megabecquerel, the unit used to express radioactivity)

Do not use PLUVICTO if:

- You are allergic to lutetium (^{177}Lu) vipivotide tetraxetan or to any of the other ingredients in this medicine

To help avoid side effects and ensure proper use, talk to your healthcare professional 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.

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.

Before administration of PLUVICTO:

You should drink plenty of water in order to remain hydrated and to urinate as often as possible during the first hours after administration to remove the radiopharmaceutical product from your body.

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

The following may interact with PLUVICTO:

- There is no information available about the use of PLUVICTO in combination with other medicines.

How to take PLUVICTO:

- PLUVICTO will be administered intravenously (into your vein) under the supervision of a health professional who is experienced in the use of radiopharmaceuticals.
- There are strict laws on the use, handling and disposal of radiopharmaceutical products. PLUVICTO will only be used in special controlled areas. This radiopharmaceutical product will only be handled and given to you by people who are trained and qualified to use it safely.

These persons will take special care for the safe use of this radiopharmaceutical product and will keep you informed of their actions.

Usual dose:

The recommended dose is 7.4 GBq (gigabecquerel, the unit used to express radioactivity).

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

Duration of the procedure

Your nuclear medicine doctor will inform you about the usual duration of the procedure.

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

Treatment monitoring

Your nuclear medicine doctor 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 nuclear medicine doctor may decide to delay, modify or stop your treatment with PLUVICTO if necessary.

After administration of PLUVICTO

For 2 days after the administration of PLUVICTO, drink plenty of water in order to remain hydrated and to urinate as often as possible to eliminate 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

- limit close contact (less than 1 meter) with:
    - others in your household for 2 days
    - children and pregnant women for 7 days;
- sleep in a separate bedroom from:
    - others in your household for 3 days
    - children for 7 days
    - pregnant women for 15 days;
- avoid sexual activity for 7 days;
- use effective birth control throughout treatment with PLUVICTO and for 14 weeks after your last dose.

Use of toilets

Take special precautions to avoid contamination during the 2 days after treatment.

- 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” below).

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.

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.

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.

Other precautions

The nuclear medicine doctor will inform you if you need to take any other special precautions after receiving this medicine. Contact your nuclear medicine doctor if you have any questions.

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.

Missed Dose:

If you miss an appointment for an administration, contact your nuclear medicine doctor as soon as possible to reschedule.

What are possible side effects from using PLUVICTO?

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

Serious side effects and what to do about them		
Symptom / effect	**Talk to your healthcare professional**	
	Only if severe	**In all cases**
VERY COMMON		
Tiredness, weakness, pale skin or shortness of breath (possible signs of low level of red blood cells) *(anemia)*		X
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)*		X
COMMON		
Passing urine less often than usual or passing much smaller amounts of urine than usual (possible sign of kidney problems) *(acute kidney injury)*		X
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)*		X
UNCOMMON		
Fast or irregular heart beat *(ventricular tachycardia)*		X
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)*		X
General swelling *(generalized edema)*	X	

Serious side effects and what to do about them		
Symptom / effect	**Talk to your healthcare professional**	
	Only if severe	**In all cases**
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*)		X
Difficulty breathing, low oxygen levels (*acute respiratory failure)*		X

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.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in the appropriate premises. Storage of radiopharmaceuticals will be in accordance with national regulations on radioactive materials.

If you want more information about PLUVICTO:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website (https://www.novartis.ca) or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

Last Revised Feb 28, 2024

PLUVICTO is a trademark.