Dosing and Administration Guide

PLUVICTO—THE FIRST AND ONLY TARGETED RADIOLIGAND THERAPY FOR PATIENTS WITH PSMA+ mCRPC

mCRPC, metastatic castration-resistant prostate cancer; PSMA+, prostate-specific membrane antigen positive.

Indication

PLUVICTO® (lutetium Lu 177 vipivotide tetraxetan) is indicated for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy.

IMPORTANT SAFETY INFORMATION

Risk From Radiation Exposure

PLUVICTO contributes to a patient's long-term cumulative radiation exposure, which is associated with an increased risk for cancer.

Minimize radiation exposure to patients, medical personnel, and household contacts during and after treatment with PLUVICTO consistent with institutional practices, patient treatment procedures, Nuclear Regulatory Commission patient-release guidance, and instructions to the patient for follow-up radiation protection.

Ensure patients increase oral fluid intake and advise them to void as often as possible to reduce bladder radiation.

To minimize radiation exposure to others, advise patients to limit close contact (less than 3 feet) with household contacts for 2 days or with children and pregnant women for 7 days, to refrain from sexual activity for 7 days, and to sleep in a separate bedroom from household contacts for 3 days, from children for 7 days, or from pregnant women for 15 days.

Please see Important Safety Information throughout and full Prescribing Information.

PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

Important note regarding use of PLUVICTO

Some of the following content is based on institutional practices or guidelines. Such procedural standards are intended to assist practitioners in providing appropriate nuclear medicine care for patients. They are not intended to establish, nor should they be used to establish, a legal standard of care. It is important to adhere to the full Prescribing Information when administering PLUVICTO injection for intravenous use.

Please check with your institution's radiation safety department and team on any further institution-specific requirements that should be followed for the administration of PLUVICTO.

PLUVICTO is a radiopharmaceutical and should be handled with appropriate safety measures to minimize radiation exposure. Use waterproof gloves and effective radiation shielding when handling PLUVICTO.[1]

PLUVICTO should be used by, or under the control of, health care providers who are qualified by specific training and experience in the safe use and handling of radiopharmaceuticals, and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radiopharmaceuticals.[1]

Any unused product or waste material should be stored for decay and disposal in accordance with local and federal laws.[1,2]

Based on institutional practices or guidelines.

Please see Important Safety Information throughout and full Prescribing Information.

Radiation safety instructions

General safety instructions[1-3]

- PLUVICTO must be handled with appropriate safety measures to minimize radiation exposure
- Should be administered only under the control of trained/licensed authorized users
- Use waterproof gloves and effective radiation shielding
- Minimize handling time
- Use tongs as needed to minimize radiation exposure
- Consider wearing a lab coat and ensure that its radioactivity level is measured with a radiation detection device before leaving the laboratory
- Wear safety glasses
- Use disposable absorbent liners on trays

Always use the principles of ALARA (as low as reasonably achievable)[3]

ALARA is the guiding principle of radiation safety. It means that even a small radiation dose should be avoided if there is no benefit to receiving it. It includes 3 basic protective measures:

TIME
Minimize time spent near radioactive source

DISTANCE
Maximize distance to radioactive source

SHIELDING
Use shielding between yourself and the radioactive source

Based on institutional practices or guidelines.

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lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

Product and dosing overview

About PLUVICTO[1]

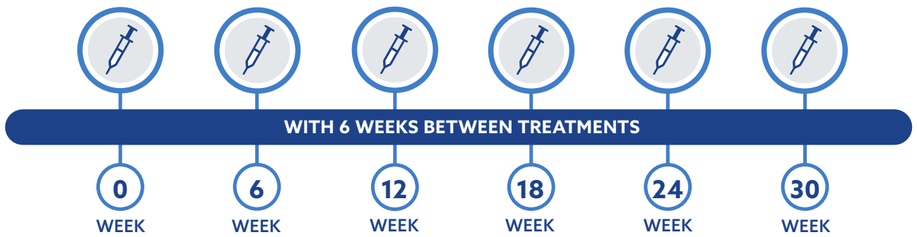
PLUVICTO is a single-dose vial injection containing 1000 MBq/mL (27 mCi/mL) of lutetium Lu 177 vipivotide tetraxetan as a clear and colorless to slightly yellow solution.

- **How PLUVICTO Is Supplied:** Colorless type I glass, 30-mL single-dose vial. The product vial is in a lead-shielded container
- **Volume:** Solution volume is adjusted from 7.5 mL to 12.5 mL to provide a total of 7.4 GBq (200 mCi) of radioactivity at the date and time of administration
- **Storage:** Store below 30°C (86°F) in the original package to protect from ionizing radiation (lead shielding). Do not freeze
- **Shelf Life:** 5 days (120 hours) from the date and time of calibration. Discard appropriately at 5 days

PLUVICTO dosing schedule

Administered every 6 weeks for up to 6 treatments[1]

- The recommended PLUVICTO dosage is 7.4 GBq (200 mCi) every 6 weeks for up to 6 treatments, or until disease progression, or unacceptable toxicity



Dose modifications for adverse reactions[1]

Management of adverse reactions may require temporary dose interruption (extending the dosing interval from 6 weeks up to 10 weeks), dose reduction, or permanent discontinuation of treatment with PLUVICTO.

The table on the next page provides recommended dose modifications of PLUVICTO for adverse reactions.

Please see Important Safety Information throughout and full Prescribing Information.

Recommended dosage modifications of PLUVICTO for adverse reactions

Adverse reaction	Severity	Dosage modification
Myelosuppression (anemia, thrombocytopenia, leukopenia, or neutropenia)	Grade 2	Withhold PLUVICTO until improvement to grade 1 or baseline.
	Grade ≥3	Withhold PLUVICTO until improvement to grade 1 or baseline. Reduce PLUVICTO dose by 20% to 5.9 GBq (160 mCi).
	Recurrent grade ≥3 myelosuppression after 1 dose reduction	Permanently discontinue PLUVICTO.
Renal toxicity	Defined as: • Confirmed serum creatinine increase (grade ≥2) • Confirmed CrCl <30 mL/min; calculate using Cockcroft-Gault with actual body weight	Withhold PLUVICTO until improvement.
	Defined as: • Confirmed ≥40% increase from baseline serum creatinine, and • Confirmed >40% decrease from baseline CrCl; calculate using Cockcroft-Gault with actual body weight	Withhold PLUVICTO until improvement or return to baseline. Reduce PLUVICTO dose by 20% to 5.9 GBq (160 mCi).
	Grade ≥3 renal toxicity	Permanently discontinue PLUVICTO.
	Recurrent renal toxicity after 1 dose reduction	Permanently discontinue PLUVICTO.
Dry mouth	Grade 2	Withhold PLUVICTO until improvement or return to baseline. Consider reducing PLUVICTO dose by 20% to 5.9 GBq (160 mCi).
	Grade 3	Withhold PLUVICTO until improvement or return to baseline. Reduce PLUVICTO dose by 20% to 5.9 GBq (160 mCi).
	Recurrent grade 3 dry mouth after 1 dose reduction	Permanently discontinue PLUVICTO.
Gastrointestinal toxicity	Grade ≥3 (not amenable to medical intervention)	Withhold PLUVICTO until improvement to grade 2 or baseline. Reduce PLUVICTO dose by 20% to 5.9 GBq (160 mCi).
	Recurrent grade ≥3 gastrointestinal toxicity after 1 dose reduction	Permanently discontinue PLUVICTO.
Fatigue	Grade ≥3	Withhold PLUVICTO until improvement to grade 2 or baseline.
Electrolyte or metabolic abnormalities	Grade ≥2	Withhold PLUVICTO until improvement to grade 1 or baseline.
AST or ALT elevation	AST or ALT >5 times ULN in the absence of liver metastases	Permanently discontinue PLUVICTO.
Other nonhematologic toxicity	Any unacceptable toxicity	Permanently discontinue PLUVICTO.
	Any serious adverse reaction that requires treatment delay of >4 weeks	Permanently discontinue PLUVICTO.
	Any recurrent grade 3 or 4 or persistent and intolerable grade 2 adverse reaction after 1 dose reduction	Permanently discontinue PLUVICTO.

ALT, alanine aminotransferase; AST, aspartate aminotransferase; CrCl, creatinine clearance; ULN, upper limit of normal.
Grading according to most current Common Terminology Criteria for Adverse Events (CTCAE).

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INJECTION FOR INTRAVENOUS USE

Not actual patient or doctor.

Prior to day of infusion[1]

- Identify patients for treatment by prostate-specific membrane antigen (PSMA) positron emission tomography imaging. PLUVICTO is approved for use only in those patients with confirmed PSMA+ metastatic castration-resistant prostate cancer who meet certain conditions
- Perform laboratory tests before and during treatment with PLUVICTO. The tests to be performed are:

Hematology (complete blood counts)

Kidney function (serum creatinine and calculated creatinine clearance)

Additional tests may be required based on physical assessment.

IMPORTANT SAFETY INFORMATION (continued)

Myelosuppression

PLUVICTO can cause severe and life-threatening myelosuppression. In the VISION study, grade 3 or 4 decreased hemoglobin (15%), decreased platelets (9%), decreased leukocytes (7%), and decreased neutrophils (4.5%) occurred in patients treated with PLUVICTO. Grade ≥3 pancytopenia occurred in 1.1% of patients (including 2 fatal events). Two deaths (0.4%) due to intracranial hemorrhage and subdural hematoma in association with thrombocytopenia were observed. One death due to sepsis and concurrent neutropenia was observed.

Perform complete blood counts before and during treatment with PLUVICTO. Withhold, reduce dose, or permanently discontinue PLUVICTO and clinically treat patients based on severity of myelosuppression.

Please see Important Safety Information throughout and full Prescribing Information.

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INJECTION FOR INTRAVENOUS USE

Day of infusion

Minimize radiation exposure[1]

- Treatment with PLUVICTO results in exposure to ionizing radiation
- In keeping with good radiation safety practices and patient management procedures, minimize radiation exposure to patients, medical personnel, and other contacts during and after treatment

Treatment room and bathroom preparation[4]

- A treatment room with a dedicated bathroom in proximity is helpful to have for the day, as the patient will need to void frequently during and on completion of the infusion. Consider using caution with patients who have urinary incontinence. Vomit, urine, and feces should be disposed according to regulations as possible radioactive waste
- Prepare bathroom to minimize potential radioactive contamination from bodily fluids in accordance with institutional guidelines

Radiation safety considerations for preparation and administration[1]

- Appropriate safety equipment, including radiation shielding, and aseptic technique, as required per federal and local laws and institutional guidelines, should be used when handling and administering PLUVICTO

Patient management considerations[1]

Encourage patients to increase oral fluids and urge them to void as often as possible to reduce bladder radiation

Dispose of urine and feces according to local and national regulations

Based on institutional practices or guidelines.

Please see Important Safety Information throughout and full Prescribing Information.

Dose preparation instructions[1]

Inspect the product visually under a shielded screen for particulate matter and discoloration prior to administration. Discard the vial if particulates or discoloration are present

Confirm the amount of radioactivity of PLUVICTO in the radiopharmaceutical vial with an appropriate dose calibrator prior to and after PLUVICTO administration

Use tongs when handling the vial to minimize radiation exposure

Do not inject PLUVICTO directly into any other intravenous solution

Use aseptic technique and radiation shielding when preparing and administering PLUVICTO

Dispose of any unused product and waste material in accordance with local and federal laws per radiation safety officer guidance

IMPORTANT SAFETY INFORMATION (continued)

Renal Toxicity

PLUVICTO can cause severe renal toxicity. In the VISION study, grade 3 or 4 acute kidney injury (3%) and increased creatinine (0.9%) occurred in patients treated with PLUVICTO.

Advise patients to remain well hydrated and to urinate frequently before and after administration of PLUVICTO. Perform kidney function laboratory tests, including serum creatinine and calculated creatinine clearance (CrCl), before and during treatment. Withhold, reduce dose, or permanently discontinue PLUVICTO based on severity of renal toxicity.

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INJECTION FOR INTRAVENOUS USE

Receiving and preparing PLUVICTO

Product and safety equipment

PLUVICTO[1]

- Regardless of administration method used, PLUVICTO is shipped from Novartis in a 30-mL vial housed in a lead container
- Prior to administration, the dose must be measured in a dose calibrator to confirm radioactivity

Radiation safety equipment[1,2]

- Dose calibrator to confirm radioactivity per batch release
- Tongs
- Disposable syringe with syringe shield if handheld infusion administration
- Disinfectant
- General personal protective equipment as directed by radiation safety officer
- Radiation detection device (eg, Geiger counter or ion chamber)

Setup and administration of PLUVICTO

General information[1,5]

- PLUVICTO is administered intravenously
- Nuclear medicine health care professionals may use methods deemed appropriate and safe, including the use of a syringe, syringe pump, gravity method, or vial with pump
- Prior to administration with PLUVICTO, a saline flush with ≥10 mL of 0.9% sterile sodium chloride must be administered to ensure patency of the intravenous line and to minimize risk of extravasation
- Manage cases of extravasation per your institutional guidelines
- PLUVICTO will be administered slowly by intravenous route and followed by a saline flush

Safety instructions for PLUVICTO[1]

- To ensure there is no product mixing, the intravenous (IV) catheter should be used only to administer PLUVICTO during the infusion
- Prior to discharge, review the PATIENT COUNSELING INFORMATION with the patient

Please see Important Safety Information throughout and full Prescribing Information.

Administration equipment[1,4]

Equipment required will depend on method of administration and institutional guidelines

Equipment	Syringe method	Gravity method	Vial with peristaltic infusion pump
0.9% sterile sodium chloride infusion bag	✓	✓	✓
Sterile tubing IV sets (with a clamp to regulate or stop flow)	✓	✓	✓
3-way stopcock	Optional		✓
Disposable syringe fitted with syringe shield and a disposable sterile needle	✓		
Filtered vent needle	Optional		
Syringe pump	Optional		
2.5-cm, 20-gauge needle (short needle)		✓	
9-cm, 18-gauge needle (long needle)		✓	✓
Infusion pump		Optional	✓
2.5-cm, 20-gauge needle (short venting needle)			✓
Peristaltic pump			✓

IMPORTANT SAFETY INFORMATION (continued)

Embryo-Fetal Toxicity

The safety and efficacy of PLUVICTO have not been established in females. Based on its mechanism of action, PLUVICTO can cause fetal harm. No animal studies using lutetium Lu 177 vipivotide tetraxetan have been conducted to evaluate its effect on female reproduction and embryo-fetal development; however, all radiopharmaceuticals, including PLUVICTO, have the potential to cause fetal harm. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with PLUVICTO and for 14 weeks after the last dose.

Based on institutional practices or guidelines.

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INJECTION FOR INTRAVENOUS USE

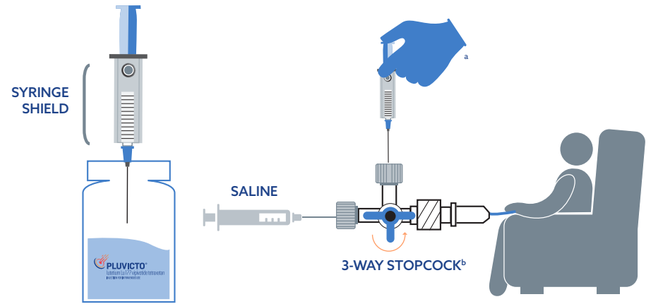
Day of infusion—administration

Methods of administration[1,4]

PLUVICTO is administered slowly via intravenous route, preceded and followed by a saline flush. PLUVICTO may be administered by 3 methods: As an injection using a disposable syringe fitted with a syringe shield (with or without a syringe pump), as an infusion using the gravity method (with or without an infusion pump), or as an infusion using the vial (with a peristaltic infusion pump).

A reduced dose of PLUVICTO should be administered using the syringe method (with or without a syringe pump) or the vial method (with a peristaltic infusion pump).

Syringe method



STEP 1: SETUP

1
- Withdraw desired radioactivity dose from PLUVICTO vial using a syringe fitted with a syringe shield and disposable sterile needle
- Optional: A filtered vent needle[c] may be used to reduce the resistance while drawing up the dose

Other methods of IV administration may be chosen per institutional practice.

STEPS 2-3: ADMINISTRATION

2
- Using the prefilled syringe, administer PLUVICTO by **slow intravenous push** within approximately 1 to 10 minutes (with a syringe pump or manually)
- Consider using a 3-way stopcock (optional) to switch from the preadministration saline flush to the injection of PLUVICTO into the port

3
- Once desired radioactivity has been administered, consider using a 3-way stopcock to switch from injection of PLUVICTO into the port to the postadministration saline flush
- Flush port with ≥10 mL of 0.9% sterile sodium chloride solution

[a] The illustration above shows the syringe method without a syringe pump. The syringe method may also be used with a syringe pump.
[b] 3-way stopcock is optional but may be considered for use. Refer to manufacturer manual.
[c] Follow appropriate guidelines and institutional practices.

Please refer to the PLUVICTO Patient-Nurse Release Information brochure to learn more about potential roles and responsibilities of different health care team members for the infusion of PLUVICTO. Note that practices may vary between institutions. Please follow your institutional practices for administration.

Based on institutional practices or guidelines.

Please see Important Safety Information throughout and full Prescribing Information.

Methods of administration[1,2] (continued)

Using the gravity method to administer a reduced dose of PLUVICTO is not recommended since it may result in delivery of the incorrect volume of PLUVICTO if the dose is not adjusted prior to administration.

Gravity method

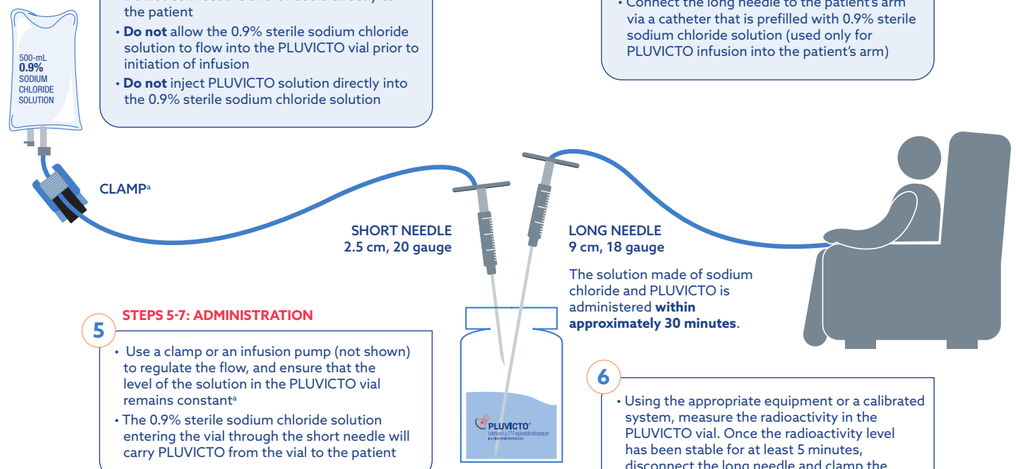
STEPS 1-4: SETUP

1
- Connect the short needle via a catheter to 500 mL of 0.9% sterile sodium chloride solution (used to transport PLUVICTO during infusion)
- Insert the short needle into the PLUVICTO vial
- The short needle **must not** touch the solution of PLUVICTO in the vial

2
- **Do not** connect the short needle directly to the patient
- **Do not** allow the 0.9% sterile sodium chloride solution to flow into the PLUVICTO vial prior to initiation of infusion
- **Do not** inject PLUVICTO solution directly into the 0.9% sterile sodium chloride solution

3
- Insert the long needle into the PLUVICTO vial
- The long needle **must touch** and be secured to the bottom of PLUVICTO vial during the entire infusion

4
- Connect the long needle to the patient's arm via a catheter that is prefilled with 0.9% sterile sodium chloride solution (used only for PLUVICTO infusion into the patient's arm)



STEPS 5-7: ADMINISTRATION

5
- Use a clamp or an infusion pump (not shown) to regulate the flow, and ensure that the level of the solution in the PLUVICTO vial remains constant[a]
- The 0.9% sterile sodium chloride solution entering the vial through the short needle will carry PLUVICTO from the vial to the patient

6
- Using the appropriate equipment or a calibrated system, measure the radioactivity in the PLUVICTO vial. Once the radioactivity level has been stable for at least 5 minutes, disconnect the long needle and clamp the 0.9% sterile sodium chloride solution

7
- Perform an intravenous flush with ≥10 mL of 0.9% sterile sodium chloride solution

[a] Monitor variations in the level and take appropriate action per your institutional practices.

The illustration above shows the gravity method without an infusion pump. The gravity method may also be used with an infusion pump.

Based on institutional practices or guidelines.

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INJECTION FOR INTRAVENOUS USE

Day of infusion—administration

Methods of administration[1] (continued)

Vial with a peristaltic infusion pump

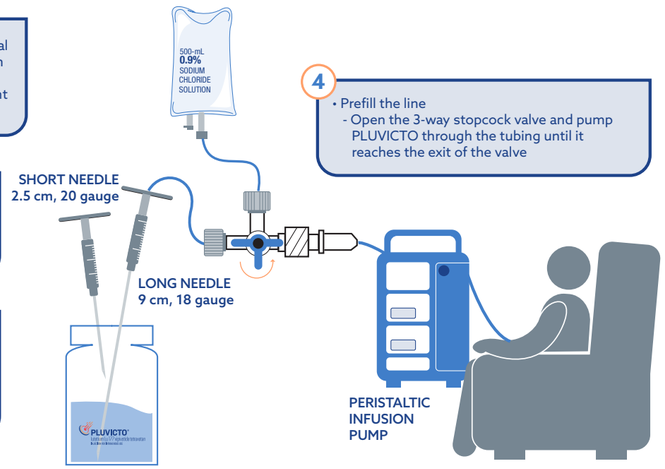
STEPS 1-4: SETUP

1
- Insert a short venting needle into the PLUVICTO vial
  - Short needle **must not** touch PLUVICTO solution in the vial
- **Do not** connect short needle directly to the patient or the peristaltic infusion pump

2
- Insert a long needle into the PLUVICTO vial
  - Long needle **must touch** and be secured to the bottom of PLUVICTO vial during the entire infusion

3
- Connect the long needle and 0.9% sterile sodium chloride solution to a 3-way stopcock valve
  - Connect the output of the 3-way stopcock valve to tubing installed on the input side of the peristaltic infusion pump

4
- Prefill the line
  - Open the 3-way stopcock valve and pump PLUVICTO through the tubing until it reaches the exit of the valve



STEPS 5-9: ADMINISTRATION

5
- Prefill the intravenous catheter
  - Open the 3-way stopcock valve to the 0.9% sterile sodium chloride solution and pump until it exits the end of the catheter tubing

6
- Connect the prefilled intravenous catheter to the patient and set the 3-way stopcock valve so PLUVICTO solution is in line with the pump

7
- Infuse a volume of PLUVICTO at a **rate of approximately 25 mL/h**

8
- Once desired radioactivity has been administered, stop the pump and change the position of the 3-way stopcock valve so that the pump is in line with the 0.9% sterile sodium chloride solution

9
- Restart the pump and infuse an intravenous flush of ≥10 mL of 0.9% sterile sodium chloride solution

Please see Important Safety Information throughout and full Prescribing Information.

Disposal[1]

- Lutetium (^{177}Lu) is prepared using 2 different sources of stable isotopes (either lutetium-176 or ytterbium-176) that require different waste management procedures
- Please consult the certificate of analysis (batch release) to identify the source of stable isotopes used and apply the appropriate waste management procedure
- Dispose of any unused product or waste material in accordance with local and federal laws and institutional radiation safety procedures and best practices

IMPORTANT SAFETY INFORMATION (continued)

Infertility

The recommended cumulative dose of 44.4 GBq of PLUVICTO results in a radiation-absorbed dose to the testes within the range where PLUVICTO may cause temporary or permanent infertility.

Adverse Reactions

The most common adverse reactions (≥20%) occurring at a higher incidence in patients who received PLUVICTO plus best standard of care (BSoC) were fatigue, dry mouth, nausea, anemia, decreased appetite, and constipation. Clinically relevant adverse reactions in <5% of patients included dry eye, vertigo, and pancytopenia (including bicytopenia).

Laboratory Abnormalities

The most common laboratory abnormalities that worsened from baseline in ≥30% of patients who received PLUVICTO plus BSoC were decreased lymphocytes, decreased hemoglobin, decreased leukocytes, decreased platelets, decreased calcium, and decreased sodium.

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INJECTION FOR INTRAVENOUS USE

Day of infusion—discharge counseling for patient and caregiver[1]

Advise patients of risk from radiation exposure and general precautions to follow during daily activities, including:

Increasing oral fluids and urinating as often as possible to reduce bladder radiation

Limiting close contact (less than 3 feet) with other people in their household for 2 days and with children or pregnant women for 7 days

Sleeping in a separate bedroom for 3 days after treatment. Sleeping in a bedroom separate from children for 7 days or pregnant women for 15 days. Refraining from sexual activity for 7 days

Contacting their health care provider for any signs or symptoms of myelosuppression or infection, such as fever, chills, sore throat, mouth ulcers, weakness, tiredness, pale skin, or spontaneous bleeding or bruising. Contacting their health care provider for any signs or symptoms of renal toxicity, such as passing urine less often than usual or passing much smaller amounts of urine than usual

Using effective contraception during treatment with PLUVICTO and for 14 weeks after the final dose

Inform patients that PLUVICTO may cause infertility

Please see Important Safety Information throughout and full Prescribing Information.

Indication

PLUVICTO® (lutetium Lu 177 vipivotide tetraxetan) is indicated for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy.

IMPORTANT SAFETY INFORMATION

Risk From Radiation Exposure

PLUVICTO contributes to a patient's long-term cumulative radiation exposure, which is associated with an increased risk for cancer.

Minimize radiation exposure to patients, medical personnel, and household contacts during and after treatment with PLUVICTO consistent with institutional practices, patient treatment procedures, Nuclear Regulatory Commission patient-release guidance, and instructions to the patient for follow-up radiation protection.

Ensure patients increase oral fluid intake and advise them to void as often as possible to reduce bladder radiation.

To minimize radiation exposure to others, advise patients to limit close contact (less than 3 feet) with household contacts for 2 days or with children and pregnant women for 7 days, to refrain from sexual activity for 7 days, and to sleep in a separate bedroom from household contacts for 3 days, from children for 7 days, or from pregnant women for 15 days.

Myelosuppression

PLUVICTO can cause severe and life-threatening myelosuppression. In the VISION study, grade 3 or 4 decreased hemoglobin (15%), decreased platelets (9%), decreased leukocytes (7%), and decreased neutrophils (4.5%) occurred in patients treated with PLUVICTO. Grade ≥3 pancytopenia occurred in 1.1% of patients (including 2 fatal events). Two deaths (0.4%) due to intracranial hemorrhage and subdural hematoma in association with thrombocytopenia were observed. One death due to sepsis and concurrent neutropenia was observed.

Perform complete blood counts before and during treatment with PLUVICTO. Withhold, reduce dose, or permanently discontinue PLUVICTO and clinically treat patients based on severity of myelosuppression.

Renal Toxicity

PLUVICTO can cause severe renal toxicity. In the VISION study, grade 3 or 4 acute kidney injury (3%) and increased creatinine (0.9%) occurred in patients treated with PLUVICTO.

Advise patients to remain well hydrated and to urinate frequently before and after administration of PLUVICTO. Perform kidney function laboratory tests, including serum creatinine and calculated creatinine clearance (CrCl), before and during treatment. Withhold, reduce dose, or permanently discontinue PLUVICTO based on severity of renal toxicity.

(continued)

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INJECTION FOR INTRAVENOUS USE

IMPORTANT SAFETY INFORMATION (continued)

Embryo-Fetal Toxicity

The safety and efficacy of PLUVICTO have not been established in females. Based on its mechanism of action, PLUVICTO can cause fetal harm. No animal studies using lutetium Lu 177 vipivotide tetraxetan have been conducted to evaluate its effect on female reproduction and embryo-fetal development; however, all radiopharmaceuticals, including PLUVICTO, have the potential to cause fetal harm. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with PLUVICTO and for 14 weeks after the last dose.

Infertility

The recommended cumulative dose of 44.4 GBq of PLUVICTO results in a radiation-absorbed dose to the testes within the range where PLUVICTO may cause temporary or permanent infertility.

Adverse Reactions

The most common adverse reactions (≥20%) occurring at a higher incidence in patients who received PLUVICTO plus best standard of care (BSoC) were fatigue, dry mouth, nausea, anemia, decreased appetite, and constipation. Clinically relevant adverse reactions in <5% of patients included dry eye, vertigo, and pancytopenia (including bicytopenia).

Laboratory Abnormalities

The most common laboratory abnormalities that worsened from baseline in ≥30% of patients who received PLUVICTO plus BSoC were decreased lymphocytes, decreased hemoglobin, decreased leukocytes, decreased platelets, decreased calcium, and decreased sodium.

Please see full Prescribing Information.

References:

1. Pluvicto. Prescribing information. Advanced Accelerator Applications USA, Inc. **2.** Ionizing radiation. Occupational Safety and Health Administration. https://www.osha.gov/ionizing-radiation/control-prevention. Accessed January 28, 2022. **3.** Centers for Disease Control and Prevention. ALARA - as low as reasonably achievable. https://www.cdc.gov/nceh/radiation/alara.html. Accessed September 15, 2021. **4.** Hope TA, Abbott A, Colucci K, et al. *J Nucl Med.* 2019;60(7):937-943. doi:10.2967/jnumed.118.230607 **5.** Data on file. VISION [PSMA-617-01] study. Novartis Pharmaceuticals Corp; 2021.

Ordering PLUVICTO through Novartis

Customer support

For ordering support or general questions, please contact Novartis Customer Support at 1-844-DOSE-AAA (1-844-367-3222). Novartis Customer Support is available from 8:00 AM to 8:00 PM ET, Monday through Friday.

Ordering

All orders must be placed through ROME. To ensure availability, orders should be placed by the Tuesday 2 weeks prior to the product calibration time. Calibration days are Tuesday through Friday. Novartis does not guarantee a requested product calibration time until the customer receives confirmation from Novartis.

Ordering confirmation

An order confirmation will be sent to your preferred contact information within 24 hours of placing an order. Please ensure that @novartis.com email addresses are not blocked by your email service.

Pharmacovigilance

Any issues pertaining to product quality or safety should be immediately reported to Novartis at www.report.novartis.com.

For more information, connect with Medical Information

+1-844-ONC-INFO (1-844-662-4636)

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To learn more about PLUVICTO® (lutetium Lu 177 vipivotide tetraxetan), visit Pluvicto-HCP.com

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East Hanover, New Jersey 07936-1080

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