PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

NOW APPROVED FOR PATIENTS WITHOUT PRIOR CHEMOTHERAPY*

A COMPREHENSIVE GUIDE TO ADMINISTERING PLUVICTO

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 pathway inhibition (ARPI) therapy, and

- are considered appropriate to delay taxane-based chemotherapy, or
- have received prior 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 others 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.

*For patients considered appropriate to delay taxane-based chemotherapy.[1]

Please see additional Important Safety Information throughout and on pages 18-19 and full Prescribing Information.

PRODUCT OVERVIEW

About PLUVICTO[1]

PLUVICTO is available as a single-dose vial and now also as a pre-filled syringe. There is no difference in efficacy between the vials and pre-filled syringes.[2]

Not actual size.

Not actual size.

Single-dose vial[1]

Product overview:

Single-dose vial containing 1000 MBq/mL (27 mCi/mL) of a clear and colorless to slightly yellow solution for intravenous use.

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 ± 10%) of radioactivity at the date and time of administration.

Pre-filled syringe[2]

Product overview:

Syringe that contains a full dose calibrated for injection on a specific day and time for each individual patient.

How PLUVICTO is supplied:

Pre-filled syringes come in Cardinal Health Nuclear & Precision Health Solutions packaging. They contain patient-specific doses that are ready to dispense.

Volume:

A 10 mL syringe (with graduations up to 12 mL) or 20 mL syringe pre-filled to provide a total of 7.4 GBq (200 mCi ± 10%) of radioactivity at the date and time of administration.

Storage[1]:

Store below 30 °C (86 °F) in the original package to protect from ionizing radiation (lead shielding). Do not freeze.

Shelf life[1]:

5 days (120 hours) from the date and time of calibration. Discard appropriately at 5 days.

GBq, gigabecquerel; MBq, megabecquerel; mCi, millicurie.

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DOSING OVERVIEW

PLUVICTO can be administered multiple ways and is administered once every 6 weeks for 6 doses[1,3,*]

- PLUVICTO solution for injection contains 7.4 GBq (200 mCi ± 10%) (at time of use)
- Slow IV injection (1 to 10 minutes) or infusion
- Pre-filled syringe

6 TREATMENTS WEEKS APART

INJECTIONS LAST LESS THAN 10 MINUTES

Not an actual patient.

The median number of doses of PLUVICTO in the PSMAfore trial (pre-chemotherapy) was 6[1]

- 63% of patients received 6 doses[4]

IV, intravenous.
*Or until disease progression, or unacceptable toxicity.[1]

IMPORTANT SAFETY INFORMATION (continued)

Myelosuppression

PLUVICTO can cause severe and life-threatening myelosuppression. In the PSMAfore study, grade 3 or 4 decreased hemoglobin (7%), decreased leukocytes (4.4%), decreased neutrophils (3.5%), and decreased platelets (2.7%) occurred in patients treated with PLUVICTO. One death occurred due to bone marrow failure during long-term follow-up in a patient who received PLUVICTO. In the VISION study, 4 myelosuppression-related deaths occurred.

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IMPORTANT NOTES ABOUT USING 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*

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]

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[1]

PLUVICTO should be used by, or under the control of, health care professionals 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]

*Based on institutional practices or guidelines.

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RECEIVING AND PREPARING PLUVICTO

See page 17 for more information about ordering PLUVICTO.

PRODUCT AND SAFETY EQUIPMENT

PLUVICTO[1,5]

- PLUVICTO is shipped from Novartis Pharmaceuticals Corporation in a 30 mL vial housed in a lead container or shipped from the radiopharmacy (Cardinal Health Nuclear & Precision Health Solutions) in a 10 mL or 20 mL pre-filled syringe
- Prior to administration, the dose must be measured in a dose calibrator to confirm radioactivity

Radiation safety equipment

- Dose calibrator to confirm radioactivity per batch release of single-dose vials or per dose document for pre-filled syringes[1]
- Tongs[1]
- Disposable syringe with syringe shield if handheld infusion administration[1]
- Radioactive material spill kit[5]
- General personal protective equipment as directed by radiation safety officer[6]
- Radiation detection device (eg, Geiger counter or ion chamber)[6]

Setup and administration of PLUVICTO

General information[1]

- PLUVICTO is administered intravenously
- An authorized health care professional may use methods deemed appropriate and safe, including the use of a syringe (with or without a syringe pump), gravity method (with or without an infusion pump), and a peristaltic infusion 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

IMPORTANT SAFETY INFORMATION (continued)

Myelosuppression (continued)

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

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RADIATION SAFETY INSTRUCTIONS

General safety instructions

- To ensure there is no product mixing, the intravenous catheter should be used only to administer PLUVICTO during the infusion[1]
- PLUVICTO must be handled with appropriate safety measures to minimize radiation exposure[1]
- Should be administered only under the control of trained/licensed authorized users[1]
- Use waterproof gloves and effective radiation shielding[1]
- Minimize handling time[6]
- Use tongs as needed to minimize radiation exposure[1]
- Consider wearing a lab coat and ensure that its radioactivity level is measured with a radiation detection device before leaving the laboratory[6]
- Wear safety glasses[6]
- Use disposable absorbent liners on trays[7,*]

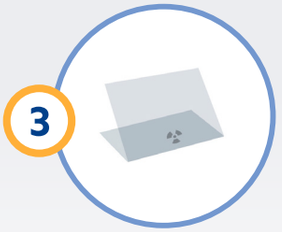
PRIOR TO DISCHARGE, REVIEW THE **PATIENT COUNSELING INFORMATION** WITH THE PATIENT

Always use the principles of ALARA (as low as reasonably achievable)[8]

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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PRIOR TO INFUSION

Identify patients for treatment by PSMA-PET scan. PLUVICTO is approved for use only in those patients with confirmed PSMA+ mCRPC who have received 1 ARPI[1]

Perform laboratory tests before and during treatment with PLUVICTO[1]

Hematology (complete blood count)

Kidney function (serum creatinine and calculated creatinine clearance)

Liver function (consider monitoring with additional laboratory tests)

Additional tests may be required based on physical assessment and other factors based on physician discretion.

ARPI, androgen receptor pathway inhibitor; mCRPC, metastatic castration-resistant prostate cancer; PET, positron emission tomography; PSMA, prostate-specific membrane antigen; PSMA+, PSMA positive.

IMPORTANT SAFETY INFORMATION (continued)

Renal Toxicity

PLUVICTO can cause severe renal toxicity. In the PSMAfore study, grade 3 or 4 acute kidney injury (1.3%) 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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DAY OF INFUSION

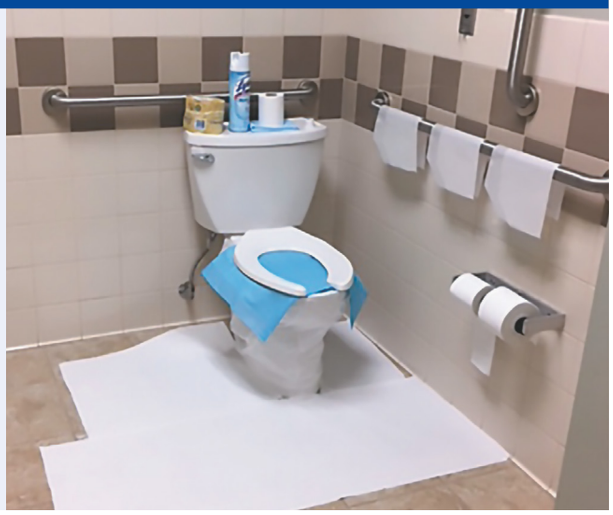
Minimize radiation exposure[1]

- 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[9,*]

- 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 after completion of the infusion. Consider using caution with patients who have urinary incontinence. Vomit, urine, and feces should be disposed of according to regulations as possible radioactive waste
- Prepare **bathroom** to minimize potential radioactive contamination from bodily fluids in accordance with institutional guidelines

*Based on institutional practices or 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 waste material according to local and federal regulations

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DAY OF INFUSION (continued)

Dose preparation instructions[1,10]

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

Confirm the amount of radioactivity of PLUVICTO in the radiopharmaceutical vial or pre-filled syringe with an appropriate dose calibrator prior to and after PLUVICTO administration

Use tongs when handling the vial or pre-filled syringe to minimize radiation exposure

Do not inject PLUVICTO directly into any other intravenous solution

Use radiation shielding and aseptic technique 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)

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, radioactive emissions, including those from PLUVICTO, can cause fetal harm. Advise males with female partners of reproductive potential to use effective contraception during treatment with PLUVICTO and for 14 weeks after the last dose.

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ADMINISTRATION EQUIPMENT

Equipment required will depend on method of administration and institutional guidelines[1,4]

EQUIPMENT	SYRINGE METHOD	GRAVITY METHOD	VIAL WITH PERISTALTIC INFUSION PUMP
0.9% sterile sodium chloride IV bag	Optional	✓	✓
Sterile tubing IV sets (with clamps to regulate or stop flow)	Optional	✓	✓
3-way stopcock	Optional		✓
Disposable syringe fitted with a syringe shield and a disposable sterile needle	✓		
Pump	Syringe pump optional	Infusion pump optional	Peristaltic pump required
2.5-cm, 20-gauge needle (short needle)		✓	
2.5-cm, 20-gauge needle (filtered venting needle)	✓		✓
Disposable sterile needle	✓		
9-cm, 18-gauge needle (long needle)		✓	✓
IV extension with two Male Luer Lock Connectors		✓	

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.

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DAY OF INFUSION—ADMINISTRATION

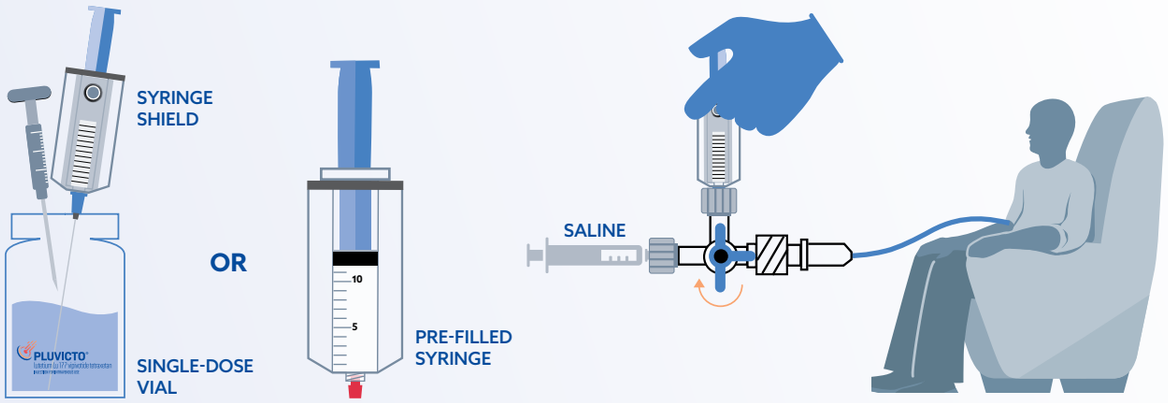
Methods of administration[1]

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[a]

WHEN USING A PRE-FILLED SYRINGE, BEGIN AT STEP 2.



STEP 1: SETUP

1. • Withdraw desired radioactivity dose from PLUVICTO vial using a syringe fitted with a syringe shield and disposable sterile needle

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

STEPS 2-3: ADMINISTRATION

2. • Using the syringe, administer PLUVICTO by **slow intravenous push** within approximately 1 to 10 minutes (with a syringe pump or manually)

3. • Flush port with ≥10 mL of 0.9% sterile sodium chloride solution

Images are for illustrative purposes only.

[a] The illustration above shows the syringe method without a syringe pump. The syringe method may also be used with a syringe pump.

Note that practices may vary between institutions. Please follow your institutional practices for administration.

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DAY OF INFUSION—ADMINISTRATION (continued)

Methods of administration[1] (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[a]

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 the PLUVICTO vial during the entire infusion

4. • Connect the long needle to the intravenous catheter or access via a catheter that is pre-filled with 0.9% sterile sodium chloride solution (used only for PLUVICTO infusion into the patient's arm)

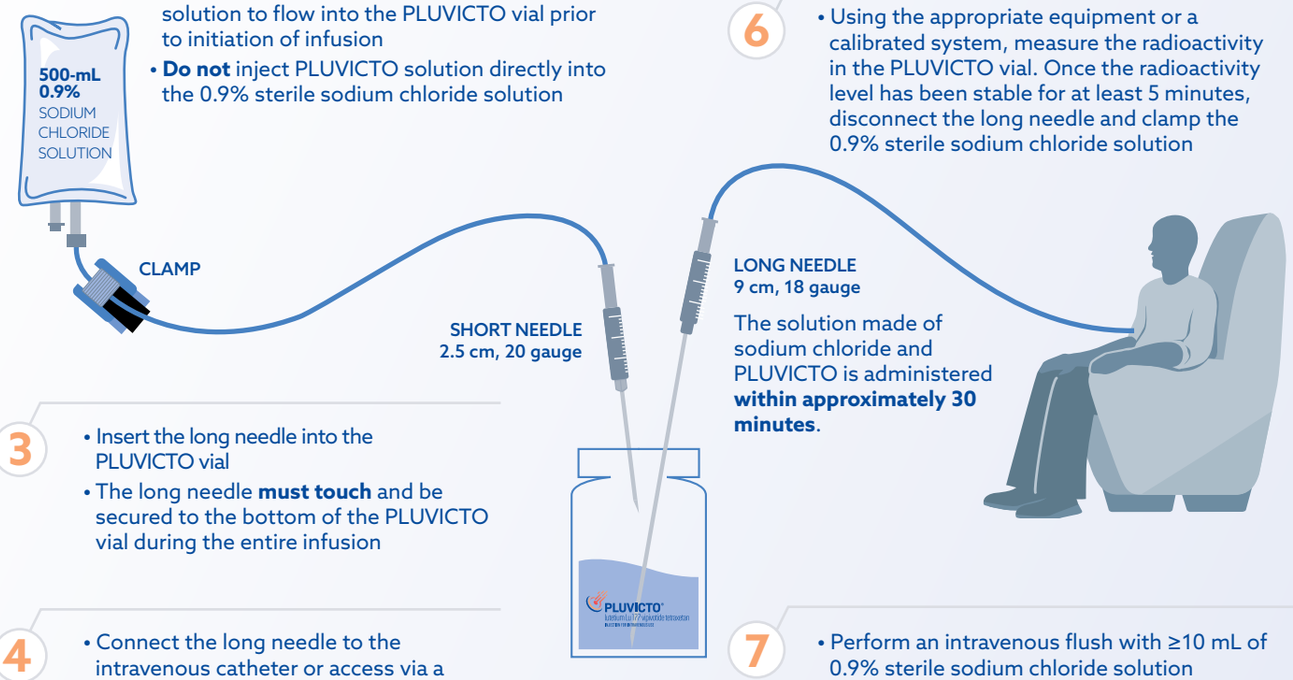
STEPS 5-7: ADMINISTRATION

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*
   • The 0.9% sterile sodium chloride solution entering the vial through the short needle will carry PLUVICTO from the vial to the patient

*Monitor variations in the level and take appropriate action per your institutional practices or guidelines.

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



Images are for illustrative purposes only.

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

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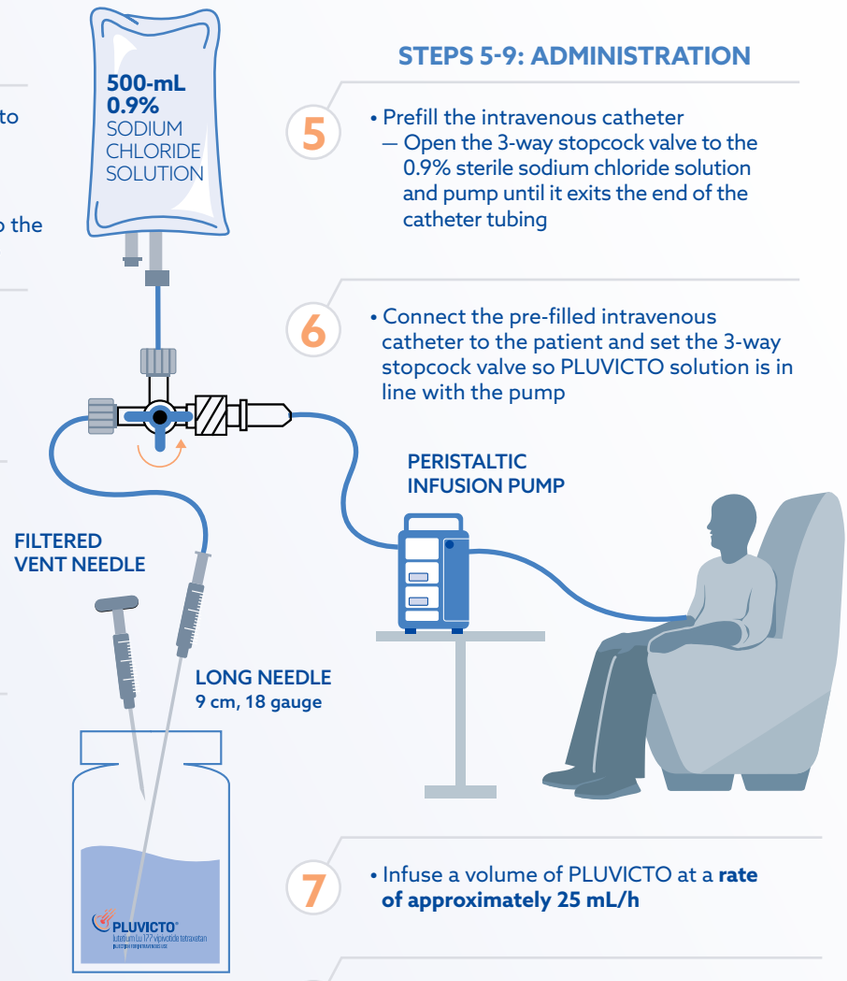
DAY OF INFUSION—ADMINISTRATION (continued)

Methods of administration[1] (continued)

VIAL WITH A PERISTALTIC INFUSION PUMP

STEPS 1-4: SETUP

1. • Insert a short filtered 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 pre-filled 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

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DAY OF INFUSION—ADMINISTRATION (continued)

Disposal[1]

- Lutetium (^{177}Lu) is prepared using 2 different sources of stable nuclides (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 nuclides used and apply the appropriate waste management procedure
- To set up waste pickup for PLUVICTO pre-filled syringes, please contact Novartis Customer Support
- 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)

Adverse Reactions and Laboratory Abnormalities

In the pooled safety population for the PSMAfore and VISION studies (N=756), the most common (≥20%) adverse reactions, including laboratory abnormalities, were decreased lymphocytes (83%), decreased hemoglobin (65%), fatigue (49%), dry mouth (46%), decreased platelets (40%), decreased estimated glomerular filtration rate (37%), nausea (35%), decreased neutrophils (31%), decreased calcium (29%), decreased sodium (27%), increased aspartate aminotransferase (26%), increased alkaline phosphatase (24%), arthralgia (22%), decreased appetite (21%), increased potassium (21%), constipation (21%), and back pain (21%).

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POST ADMINISTRATION—DISCHARGE COUNSELING FOR PATIENTS AND CAREGIVERS

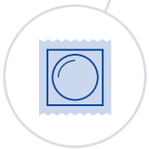
Advise patients of risk from radiation exposure and general precautions to follow during daily activities, including[1]:

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**

Contacting their health care professionals 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; refraining from sexual activity for **7 days** after each treatment

Inform patients that PLUVICTO may cause infertility

ENSURE PATIENTS ARE MONITORED FOR ADVERSE REACTIONS DURING AND AFTER TREATMENT

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PLUVICTO IS ACCESSIBLE FOR MOST INSURED PATIENTS*

100%

OF MEDICARE FFS PATIENTS ARE COVERED TO LABEL[11]

95%

OF MEDICARE ADVANTAGE PATIENTS ARE COVERED TO LABEL[11]

- **>80% of insured patients have favorable coverage for PLUVICTO as of January 2025**[11]

The other 20% do not have published policies and/or cases may be decided on an individual basis. Follow up with the patient's plan to determine coverage.

>8 of 10

COVERED PATIENTS PAID $0 OUT-OF-POCKET PER INFUSION[12]

A review of claims data between Q1 2023-Q2 2024 indicated that approximately 85% of patients paid $0 for the product. For remaining patients, the out-of-pocket cost for the product varies and may be as high as the total cost of the product. Additional out-of-pocket costs may be incurred related to treatment, including but not limited to administration fees.

Coverage determined based on patients treated with at least one ARPI and one taxane.

QUESTIONS? CALL NOVARTIS PATIENT SUPPORT 1-844-638-7222, MONDAY-FRIDAY, 8:00 AM-8:00 PM ET, EXCLUDING HOLIDAYS

FFS, fee for service.

*The information provided in this communication is not a guarantee of coverage and patient out-of-pocket costs may vary. Actual coverage and reimbursement decisions are made by individual payers following the receipt of claims and will vary.

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NOVARTIS PATIENT SUPPORT™: A DEDICATED TEAM FOR YOU AND YOUR PATIENTS

Novartis Patient Support is a comprehensive program designed to help your patients start, stay, and save on PLUVICTO

We provide support throughout your patient's journey with:

Insurance & Reimbursement

Support includes:
- Benefits verification
- Prior authorization requirements
- Appeals support
- Billing, coding, and reimbursement education

Financial Support

Eligible patients may pay as little as $0* per dose. Enrollment is required to determine eligibility and participation.

Acquisition

Support includes:
- New treating site onboarding and access to ordering platform
- Real-time delivery tracking

Patient Education

Live 1-on-1 support is available for patients starting treatment. Our Patient Navigators can help answer the most common treatment questions.

Our team is available to assist you every step of the way

For insurance and financial support for your office and 1-on-1 patient education, call: **1-844-638-7222**.

For product ordering and delivery, call: **1-844-367-3222**.

Benefit investigation can be completed in less than 2 business days.†
Click here and fax the Start Form to **1-844-638-7329**.

ASK YOUR NOVARTIS ONCOLOGY SPECIALIST TO CONNECT YOU WITH YOUR LOCAL ACCESS & REIMBURSEMENT REPRESENTATIVE TO HELP ANSWER DETAILED QUESTIONS ON PAYER COVERAGE, PATIENT AFFORDABILITY, PURCHASING, PRICING, AND REIMBURSEMENT

*Limitations apply. Valid only for those patients with commercial insurance. Not valid under Medicare or any other federal or state program. Offer subject to a maximum benefit per course of treatment. See complete Terms and Conditions in the Start Form for details.
†Primary plans only; add additional 1-2 days if a secondary plan coverage review is required.

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INDICATION AND IMPORTANT SAFETY INFORMATION

Indication

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- are considered appropriate to delay taxane-based chemotherapy, or
- have received prior 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 others 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 PSMAfore study, grade 3 or 4 decreased hemoglobin (7%), decreased leukocytes (4.4%), decreased neutrophils (3.5%), and decreased platelets (2.7%) occurred in patients treated with PLUVICTO. One death occurred due to bone marrow failure during long-term follow-up in a patient who received PLUVICTO. In the VISION study, 4 myelosuppression-related deaths occurred.

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

Renal Toxicity

PLUVICTO can cause severe renal toxicity. In the PSMAfore study, grade 3 or 4 acute kidney injury (1.3%) 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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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, radioactive emissions, including those from PLUVICTO, can cause fetal harm. Advise males 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 and Laboratory Abnormalities

In the pooled safety population for the PSMAfore and VISION studies (N=756), the most common (≥20%) adverse reactions, including laboratory abnormalities, were decreased lymphocytes (83%), decreased hemoglobin (65%), fatigue (49%), dry mouth (46%), decreased platelets (40%), decreased estimated glomerular filtration rate (37%), nausea (35%), decreased neutrophils (31%), decreased calcium (29%), decreased sodium (27%), increased aspartate aminotransferase (26%), increased alkaline phosphatase (24%), arthralgia (22%), decreased appetite (21%), increased potassium (21%), constipation (21%), and back pain (21%).

Please see full Prescribing Information.

References:

1. Pluvicto. Prescribing information. Novartis Pharmaceuticals Corp. **2.** Data on file. Pre-filled syringe information. Novartis Pharmaceuticals Corp; 2024. **3.** Sartor O, de Bono J, Chi KN, et al; VISION Investigators. Lutetium-177–PSMA-617 for metastatic castration-resistant prostate cancer. *N Engl J Med*. 2021;385(12):1091-1103. doi:10.1056/NEJMoa2107322 **4.** Morris MJ, Castellano D, Herrmann K, et al; PSMAfore Investigators. ^{177}Lu-PSMA-617 versus a change of androgen receptor pathway inhibitor therapy for taxane-naive patients with progressive metastatic castration-resistant prostate cancer (PSMAfore): a phase 3, randomised, controlled trial. *Lancet*. 2024;404(10459)(suppl 1):1227-1239. doi:10.1016/S0140-6736(24)01653-2 **5.** Data on file. Medical illustrations for treatment guide. Novartis Pharmaceuticals Corp; 2024. **6.** Occupational Safety and Health Administration. Ionizing radiation. https://www.osha.gov/ionizing-radiation/control-prevention. Accessed October 30, 2023. **7.** Occupational Safety and Health Administration. Guidelines for cytotoxic (antineoplastic) Drugs. https://www.osha.gov/enforcement/directives/std-01-23-001. Accessed November 2, 2023. **8.** Centers for Disease Control and Prevention. Guidelines for ALARA - as low as reasonably achievable. https://www.cdc.gov/radiation-health/safety/alara.html. Accessed December 4, 2024. **9.** Hope TA, Abbott A, Colucci K, et al. NANETS/SNMMI procedure standard for somatostatin receptor-based peptide receptor radionuclide therapy with ^{177}Lu-DOTATATE. *J Nucl Med*. 2019;60(7):937-943. doi:10.2967/jnumed.118.230607 **10.** Data on file. PLUVICTO Prefilled Syringe Checklist 8.24. **11.** Data on file. MMIT Market Access Claims. March 2025. **12.** Data on file. PLUVICTO IQVIA LAAD data analysis. Novartis Pharmaceuticals Corp; Jan 2023 to Jun 2024.

TREATING PATIENTS WITH PLUVICTO

Learn more about how to monitor your patients for adverse reactions during and after treatment and how to dose modify PLUVICTO

Watch a video to see a multidisciplinary team discuss dosing and administration for PLUVICTO

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 pathway inhibition (ARPI) therapy, and

- are considered appropriate to delay taxane-based chemotherapy, or
- have received prior 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 others 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 additional Important Safety Information throughout and on pages 18-19 and full Prescribing Information.

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