



**FDA 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 20-21 and full Prescribing Information.

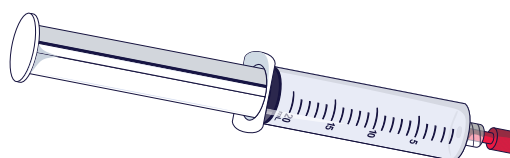
PRODUCT OVERVIEW

About PLUVICTO^{1,2}

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.^{1,2}



Not actual size.



Not actual size.

Single-dose vial¹

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

Storage¹:

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

Shelf life¹:

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

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

Pre-filled syringe^{1,2}

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:

Novartis partners with third-party radiopharmacies to deliver pre-filled syringes to our customers. As part of that process, your account will need to be onboarded to order PLUVICTO pre-filled syringe. Ordering requires additional prescription information.

Volume:

20 mL syringe pre-filled to provide a total of 7.4 GBq (200 mCi \pm 10%) of radioactivity at the date and time of administration.

Please see Important Safety Information throughout and on pages 20-21 and full Prescribing Information.



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 \pm 10%) (at time of use)
- Slow IV injection (1 to 10 minutes) or infusion
- Pre-filled syringe



Not an actual patient.

6 TREATMENTS WEEKS APART

INJECTIONS LAST LESS THAN 10 MINUTES

The median number of doses of PLUVICTO in the PSMAfore trial (pre-chemotherapy) was 6¹

- 63% of patients received 6 doses⁴

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.

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 PLUVICTO¹



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 PLUVICTO¹



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 radiopharmaceuticals¹



Any unused radioactive product or waste material should be stored for decay and disposal in accordance with local and federal laws¹

*Based on institutional practices or guidelines.

Please see Important Safety Information throughout and on pages 20-21 and full Prescribing Information.



RECEIVING AND PREPARING PLUVICTO

See page 19 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 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^{1,2}
- Tongs¹
- Disposable syringe with syringe shield if handheld infusion administration¹
- Radioactive material spill kit⁶
- General personal protective equipment as directed by radiation safety officer⁶
- Radiation detection device (eg, Geiger counter or ion chamber)⁶

Setup and administration of PLUVICTO

General information¹

- 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.

Please see additional Important Safety Information throughout and on pages 20-21 and full Prescribing Information.



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 infusion¹
- PLUVICTO must be handled with appropriate safety measures to minimize radiation exposure¹
- Should be administered only under the control of trained/licensed authorized users¹
- Use waterproof gloves and effective radiation shielding¹
- Wear safety glasses⁶
- Minimize handling time⁶
- Use tongs as needed to minimize radiation exposure¹
- Consider wearing a lab coat and ensure that its radioactivity level is measured with a radiation detection device before leaving the laboratory⁶
- Use disposable absorbent liners on trays^{7,*}

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

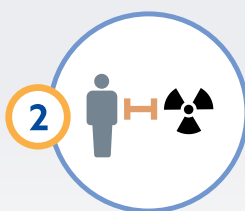
Always use the principles of ALARA (as low as reasonably achievable)⁸

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:



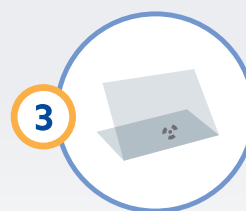
TIME

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.

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 ARPI¹

Perform laboratory tests before and during treatment with PLUVICTO¹



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.

DAY OF INFUSION

Minimize radiation exposure¹

- 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. Consider using caution with patients who have urinary incontinence. For patients with urinary incontinence, be sure to follow guidelines from your institution. 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 administration¹

- 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 considerations¹



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



Dispose of radioactive waste material according to local and federal regulations

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 radioactive 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.

ADMINISTRATION EQUIPMENT

Equipment required will depend on method of administration and institutional guidelines^{1,5}

EQUIPMENT	SYRINGE METHOD	GRAVITY METHOD	VIAL WITH PERISTALTIC INFUSION PUMP
0.9% sterile sodium chloride IV bag	Optional	✓	✓
IV administration set (with clamps to regulate or stop flow)	Optional	✓	Manufacturer-specific peristaltic pump administration set
3-way stopcock	Optional	Optional	✓
Disposable syringe fitted with a syringe shield	✓		
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)	✓		✓
9 cm, 18-gauge needle (long needle)	Required when on-site dose preparation from a vial is necessary	✓	✓
IV extension with two Male Luer Lock Connectors	✓	✓	✓
Manufacturer-specific peristaltic pump administration set			✓

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.

Please see additional Important Safety Information throughout and on pages 20-21 and full [Prescribing Information](#).



DAY OF INFUSION—METHODS OF ADMINISTRATION

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).¹

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). When using the gravity method for a reduced dose, adjust the PLUVICTO dose before the administration to avoid the delivery of an incorrect volume of PLUVICTO.¹

SYRINGE METHOD^{1,*}

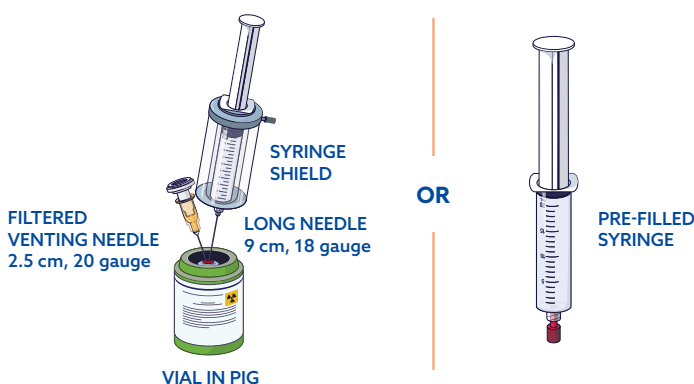
SETUP

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

STEP 1:

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

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



ADMINISTRATION

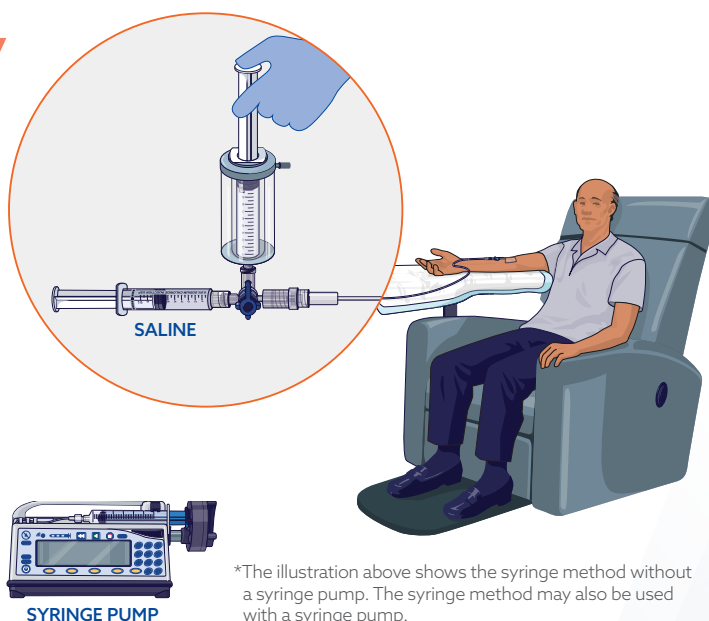
STEP 2:

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

STEP 3:

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

Images are for illustrative purposes only. Illustrations may show different positioning and/or scale of equipment than actual clinical setup for administration.

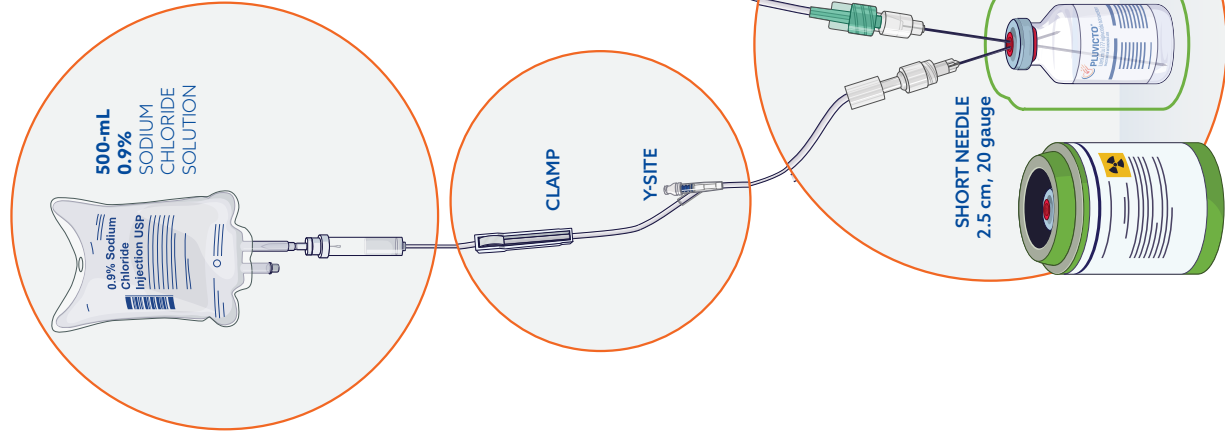


*The illustration above shows the syringe method without a syringe pump. The syringe method may also be used with a syringe pump.

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

DD 1,*

Method for a reduced dose, adjust the PLUVICTO dose before the administration incorrect volume of PLUVICTO.



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PLUVICTO is administered slowly via intravenous route, preceded and followed by a flush of 0.9% sodium chloride. PLUVICTO may be administered by 3 methods: As an injection using a disposable syringe fitted with a 25-gauge needle, preceded and followed by a flush of 0.9% sodium chloride (with or without a syringe pump), as an infusion using the gravity method (with a syringe pump), or as an infusion using the vial (with a peristaltic infusion pump).¹ A reduced dose of PLUVICTO should be administered using the syringe method (with a syringe pump) or the vial method (with a peristaltic infusion pump).¹

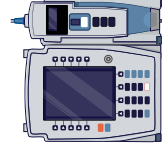
ADMINISTRATION

STEP 4:

Use a clamp or an infusion pump to regulate the flow and ensure the solution in the PLUVICTO vial is constant.¹

The 0.9% sterile sodium chloride solution entering the vial through the PLUVICTO from the syringe pump.

*Monitor variations in the level of the solution in the PLUVICTO vial per your institutional protocol.



INFUSION PUMP

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

STEP 5:

Once the level of radiation is at least 5 minutes, clamp the pump to stop the flow of the solution into the PLUVICTO vial from the long needle.

STEP 6:

Flush the patient's intravenous line with ≥10 mL of 0.9% sterile sodium chloride solution.



PERISTALTIC INFUSION PUMP¹

PLUVICTO is administered slowly via intravenous route, preceded and followed by 0.9% sterile sodium chloride flush. PLUVICTO may be administered by 3 methods: As an injection using a disposable syringe fitted with a 25-gauge needle (with or without a syringe pump), as an infusion using the gravity method (with a gravity infusion pump), or as an infusion using the vial (with a peristaltic infusion pump).¹ A reduced dose of PLUVICTO should be administered using the syringe method (with a syringe pump) or the vial method (with a peristaltic infusion pump).¹

Insert the 25-gauge needle into the

stopcock of the PLUVICTO

vial. The vial should be secured to the peristaltic

pump using the PLUVICTO vial.

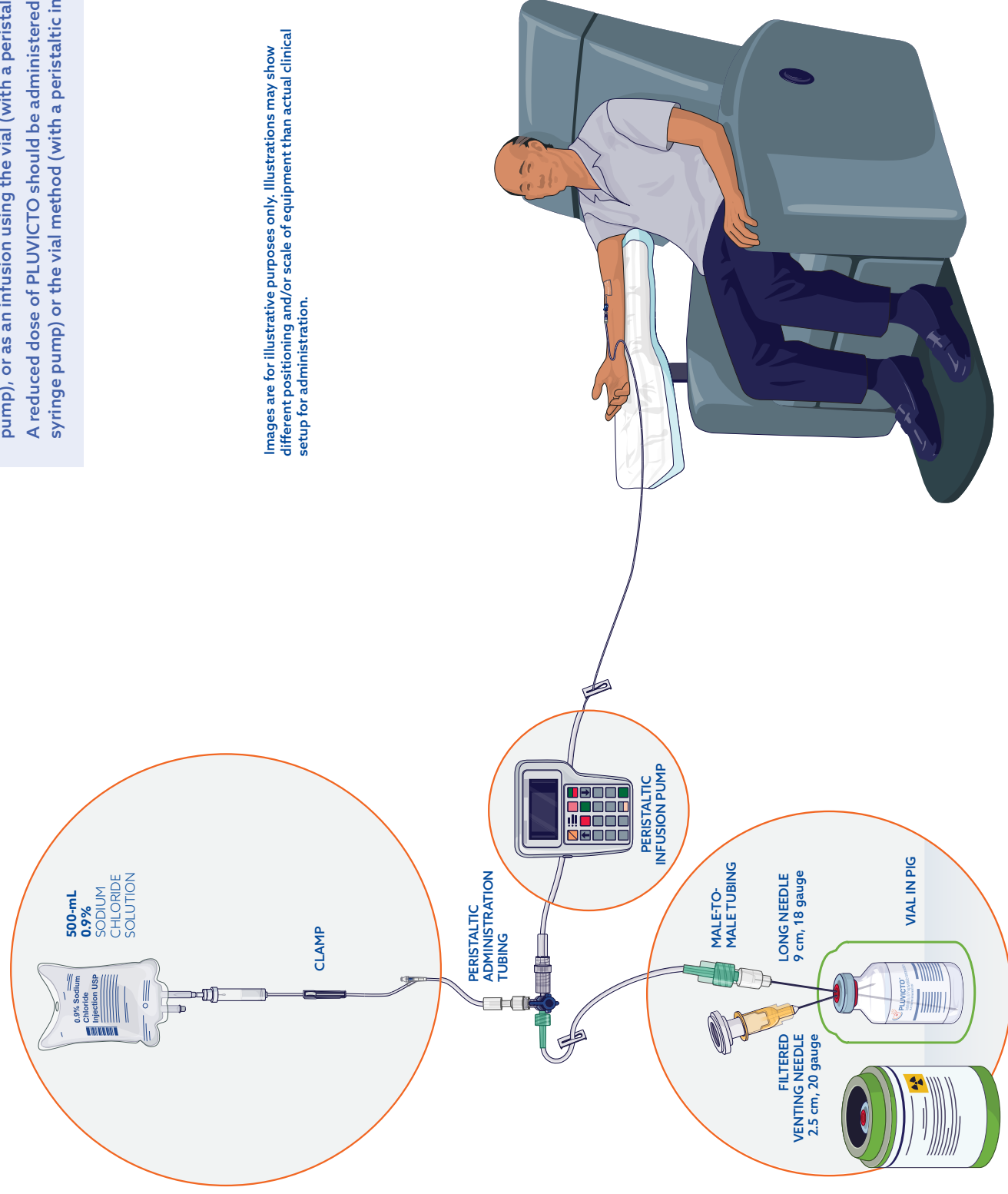
The vial should be secured to the pump during the

infusion. The male-to-male tubing and the sodium chloride

flush syringe should be connected to the distal end of

the stopcock using the

0.9% sterile sodium chloride flush through the peristaltic



ADMINISTRATION

STEP 5:

Connect the pre-filled long needle to the pre-filled peristaltic pump. Begin infusion via intravenous catheter.

STEP 6:

Adjust the 3-way stopcock to the PLUVICTO vial in the pump. Begin infusion at an approximate

STEP 7:

Once desired radioactivity has been administered, stop the pump. The position of the 3-way stopcock should be adjusted so that the pump is infusing the sodium chloride solution.

STEP 8:

Restart the pump at a rate of 0.1 mL/h. Flush of ≥ 10 mL of 0.9% sterile sodium chloride solution.

Images are for illustrative purposes only. Illustrations may show different positioning and/or scale of equipment than actual clinical setup for administration.

DAY OF INFUSION—METHODS OF ADMINISTRATION (continued)

Disposal¹



- To set up post-administration pickup for PLUVICTO pre-filled syringe, please contact Cardinal Health
- Dispose of any radioactive waste in accordance with local and federal laws, as well as institutional radiation safety procedures

Note: In exceptional situations, to ensure patient access and guarantee continuity of supply, treatment centers may receive doses of PLUVICTO prepared with carrier-added lutetium. In these circumstances, Customer Support will contact your institution prior to shipment.

FOR MORE QUESTIONS, CALL CUSTOMER SUPPORT AND/OR ASK YOUR ONCOLOGY SPECIALIST TO BE REFERRED TO YOUR RTS REPRESENTATIVE

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 ($\geq 20\%$) 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%).

RTS, Radioligand Therapy Specialist.

Please see additional Important Safety Information throughout and on pages 20-21 and full Prescribing Information.

 **PLUVICTO**[®]
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

POST ADMINISTRATION—WHAT PATIENTS CAN EXPECT AFTER EACH DOSE

Reduce radiation exposure

The body, blood, and urine give off radiation for a while after getting PLUVICTO. Here are some tips for patients to help reduce overall exposure to themselves and others:



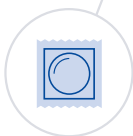
Limit close contact (less than 3 feet) with others for **2 days** or with children and pregnant women for **7 days**¹



Stay hydrated and urinate as much as they can¹

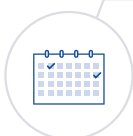


Sleep in a separate room from others for **3 days**, from children for **7 days**, or from pregnant women for **15 days**¹



No sexual activity for **7 days**. Use protection after that¹

Understanding targeted radiation



Radiation from PLUVICTO does not stay in the body long. Within 2 days, over half of the radiation will leave the body^{1,11}



Radiation exposure to others is about the same as 3 flights. After one dose of PLUVICTO, a care partner may be exposed to the same amount of radiation as 3 flights from the East Coast to the West Coast of the United States^{12,13}

ENSURE PATIENTS ARE MONITORED
FOR ADVERSE REACTIONS DURING
AND AFTER TREATMENT

PLUVICTO IS ACCESSIBLE FOR MOST INSURED PATIENTS*

100%

OF MEDICARE FFS PATIENTS
ARE COVERED TO LABEL¹⁴

95%

OF MEDICARE ADVANTAGE
PATIENTS ARE COVERED
TO LABEL¹⁴

• >80% of insured patients have favorable coverage for PLUVICTO as of January 2025¹⁴

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 INFUSION¹⁵

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 AT
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.

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 patients' journey with:



Benefits investigation

- Prior authorization requirements
- Appeals support
- Billing, coding, and reimbursement education (for treatment centers only)



Financial Support

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



Accessing Treatment

- Access to [ROME] ordering platform
- Help with product ordering
- Real-time delivery tracking
- Treatment center locator
- Additional offerings available for referring sites



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; an additional 1-2 days if a secondary plan coverage review is required.



INDICATION AND IMPORTANT SAFETY 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 pathway inhibition (ARPI) therapy, and

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IMPORTANT SAFETY INFORMATION

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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.

IMPORTANT SAFETY INFORMATION (continued)

Embryo-Fetal Toxicity

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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 ($\geq 20\%$) 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:

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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 20-21 and full [Prescribing Information](#).



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