PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

A COMPREHENSIVE GUIDE TO ADMINISTERING PLUVICTO® IN PSMA+ METASTATIC PROSTATE CANCERS

In mAPMN/S PC (also known as mHSPC) in combination with ARPI and mAPMR PC (also known as mCRPC) after only 1 ARPI, choose PLUVICTO at the earliest eligible opportunity[1]

Indications

PLUVICTO® (lutetium Lu 177 vipivotide tetraxetan) is indicated in combination with androgen receptor pathway inhibitor (ARPI) therapy for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic androgen pathway modulation-naïve or -sensitive (mAPMN/S) prostate cancer.

PLUVICTO is indicated for the treatment of adult patients with PSMA-positive metastatic androgen pathway modulation-resistant (mAPMR) prostate cancer who have been treated with 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 others 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 room from others 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 21-22 and full Prescribing Information.

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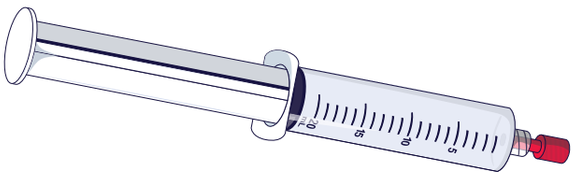
PRODUCT OVERVIEW

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.

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[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 syringes. Ordering requires additional prescription information.

Volume:

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

Actor portrayals.

- The recommended dosage of PLUVICTO is 7.4 GBq (200 mCi) every 6 weeks for 6 doses, or until disease progression or unacceptable toxicity[1]
- Patients receiving PLUVICTO for metastatic prostate cancer should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy[1]

The median number of doses of PLUVICTO in the PSMAddition trial in mAPMN/S PC (mHSPC) (+ ARPI) was 6[1]

- 85.6% of patients received 6 doses[4]

The median number of doses of PLUVICTO in the PSMAfore trial in mAPMR PC (mCRPC) after only 1 ARPI was 6[1]

- 63% of patients received 6 doses[5]

ARPI, androgen receptor pathway inhibitor; IV, intravenous; mAPMN/S PC, metastatic androgen pathway modulation-naive or -sensitive prostate cancer; mAPMR PC, metastatic androgen pathway modulation-resistant prostate cancer; mCRPC, metastatic castration-resistant prostate cancer; mHSPC, metastatic hormone-sensitive prostate cancer.

IMPORTANT SAFETY INFORMATION (continued)

Myelosuppression

- PLUVICTO can cause severe and life-threatening myelosuppression. In clinical trials (PSMAddition, PSMAfore, VISION) grade 3 or 4 decreased hemoglobin (ranged from 4.3-15%), decreased leukocytes (4.4-7%), decreased neutrophils (3.5-4.5%), and decreased platelets (1.1-9%) occurred in patients treated with PLUVICTO. 5 myelosuppression-related deaths have occurred, including one due to bone marrow failure during long-term follow-up.

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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 radioactive 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 19 for more information about accessing PLUVICTO.

PRODUCT AND SAFETY EQUIPMENT

PLUVICTO[1,6]

- 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]
- Tongs[1]
- Disposable syringe with syringe shield if handheld infusion administration[1]
- Radioactive material spill kit[7]
- General personal protective equipment as directed by radiation safety officer[7]
- Radiation detection device (eg, Geiger counter or ion chamber)[7]

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]
- Wear safety glasses[7]
- Minimize handling time[7]
- 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[7]
- Use disposable absorbent liners on trays[8,*]

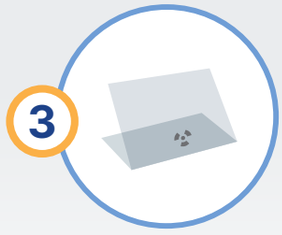
PRIOR TO DISCHARGE, REVIEW THE **PATIENT COUNSELING INFORMATION** WITH THE PATIENT

Always use the principles of ALARA (as low as reasonably achievable)[9]

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 from 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 patients with confirmed PSMA+ mAPMN/S PC (mHSPC) + ARPI or PSMA+ mAPMR PC (mCRPC) after only 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.

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 clinical trials grade 3 or 4 acute kidney injury (ranged from 1.3-3.4%) 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

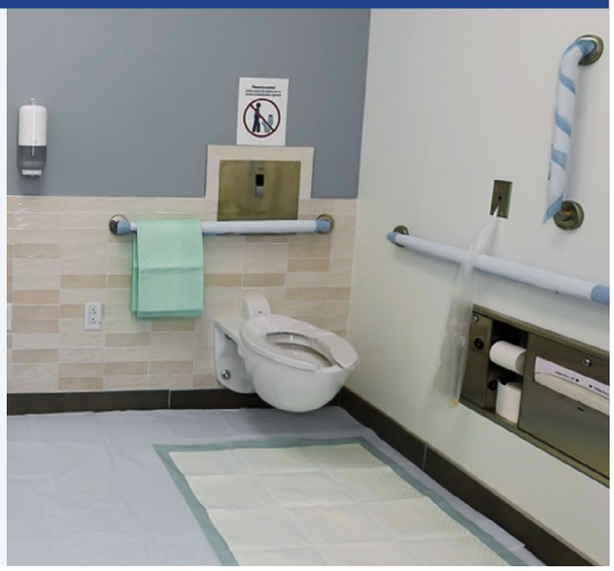
Minimize radiation exposure[1]

- 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[10,*]

- 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 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 radioactive waste material according to local and federal regulations

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DAY OF INFUSION (continued)

Dose preparation instructions[1,11]

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.

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ADMINISTRATION EQUIPMENT

Equipment required will depend on method of administration and institutional guidelines[1,6]

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.

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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,*]

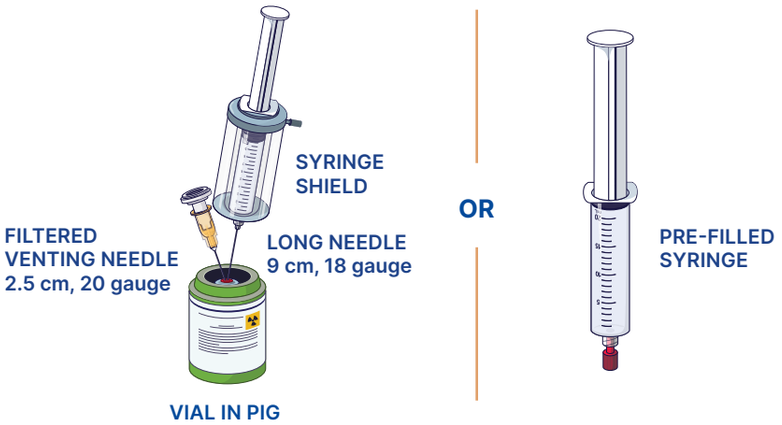
SETUP

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.



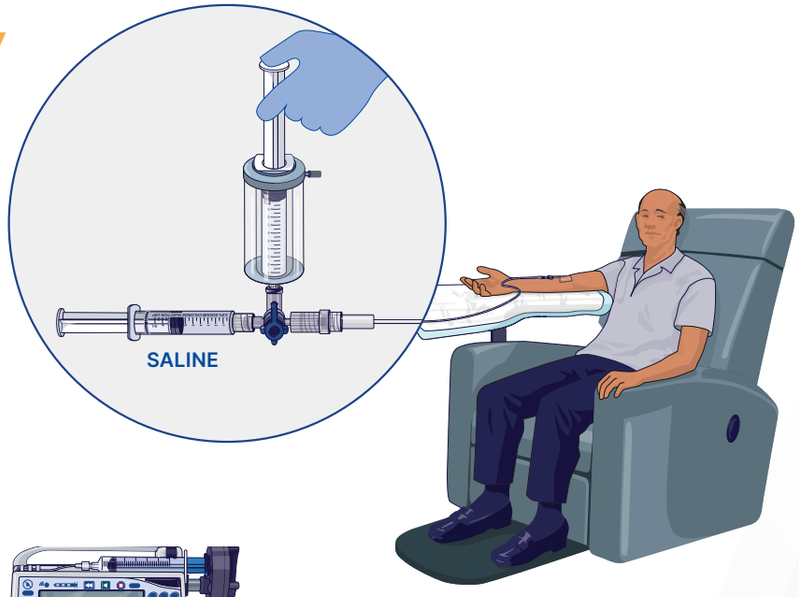
ADMINISTRATION

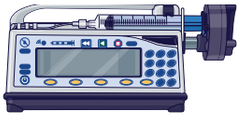
STEP 2:

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.




SYRINGE PUMP

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.

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GRAVITY METHOD[1,*]

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.

SETUP

STEP 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

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.

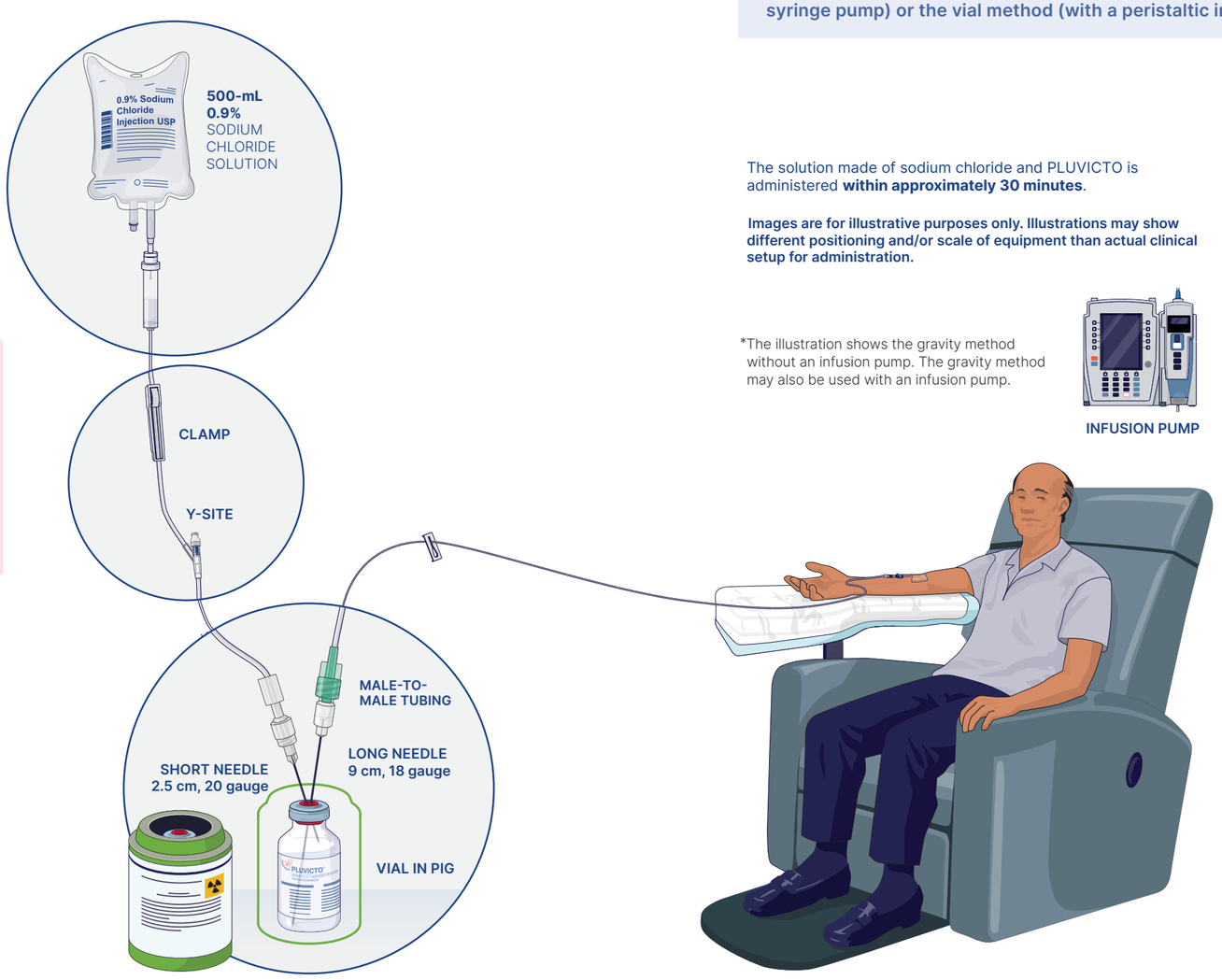
STEP 2:

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

STEP 3:

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).



DAY OF INFUSION—METHODS OF ADMINISTRATION (continued)

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).[1]

ADMINISTRATION

The solution made of sodium chloride and PLUVICTO is administered **within approximately 30 minutes**.

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

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

INFUSION PUMP

STEP 4:

Use a clamp or an infusion* pump 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.

STEP 5:

Once the level of radioactivity is stable for at least 5 minutes, clamp or stop the infusion pump to stop the flow of 0.9% sterile sodium chloride solution into the vial, and disconnect the vial from the long needle line.

STEP 6:

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

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VIAL WITH A PERISTALTIC INFUSION PUMP[1]

SETUP

STEP 1:

Insert a short filtered venting needle into the PLUVICTO vial.

— Short needle **must not** touch PLUVICTO solution in the vial

Do not connect the short needle directly to the patient or the peristaltic infusion pump.

STEP 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

STEP 3:

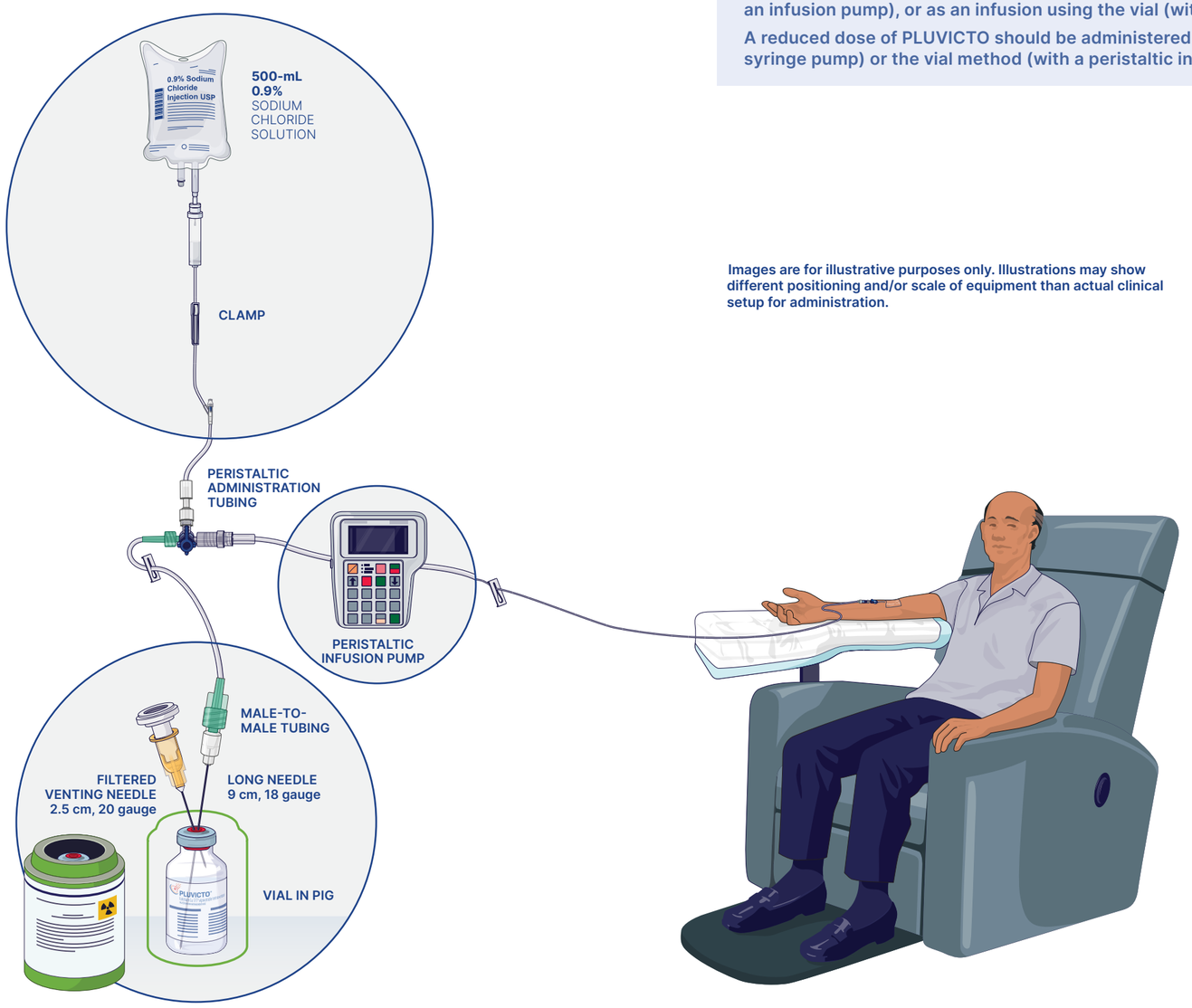
Connect both the male-to-male tubing and the tubing from the 0.9% sterile sodium chloride solution bag to the 3-way stopcock.

Open the stopcock toward the male-to-male tubing and prefill it with 0.9% sterile sodium chloride until fluid reaches the distal end of the tubing.

STEP 4:

Connect the output of the 3-way stopcock to the input of the manufacturer-specific peristaltic pump tubing.

Open the stopcock to allow 0.9% sterile sodium chloride solution to flow through until it reaches the distal end of the peristaltic pump tubing.



DAY OF INFUSION—METHODS OF ADMINISTRATION (continued)

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).[1]

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

ADMINISTRATION

STEP 5:

Connect the pre-filled male-to-male tubing to the long needle. Connect the output of the pre-filled peristaltic pump tubing to the patient's intravenous catheter.

STEP 6:

Adjust the 3-way stopcock so that the PLUVICTO vial is in line with the peristaltic pump. Begin infusion of the full PLUVICTO dose at an **approximate rate of 25 mL/hour**.

STEP 7:

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.

STEP 8:

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 on pages 21-22 and full Prescribing Information.

DAY OF INFUSION—METHODS OF ADMINISTRATION (continued)

Disposal[1]

- To set up post-administration pickup for PLUVICTO pre-filled syringes, 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

RTS, Radioligand Therapy Specialist.

IMPORTANT SAFETY INFORMATION (continued)

Adverse Reactions and Laboratory Abnormalities

- In the pooled safety population for the PSMAddition, PSMAfore and VISION studies (N=1320), the most common (≥20%) adverse reactions, including laboratory abnormalities, were decreased lymphocytes (86%), decreased hemoglobin (68%), fatigue (51%), dry mouth (46%), decreased neutrophils (35%), nausea (35%), decreased platelets (33%), decreased estimated glomerular filtration rate (28%), increased aspartate aminotransferase (25%), decreased sodium (22%), increased magnesium (22%), increased potassium (21%), decreased calcium (21%), and increased alkaline phosphatase (20%).

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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:

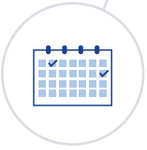
Limit close contact (less than 3 feet) with others for **2 days** or with children and pregnant women for **7 days**[1]

Stay hydrated and urinate as much as they can[1]

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 that[1]

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[1,12]

Radiation exposure to others is about the same as 3 East Coast to West Coast flights. After 1 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[13,14]

ENSURE PATIENTS ARE MONITORED FOR ADVERSE REACTIONS DURING AND AFTER TREATMENT

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PLUVICTO IS ACCESSIBLE FOR MOST INSURED PATIENTS*

>80%

OF MEDICARE ELIGIBLE PATIENTS HAVE FAVORABLE COVERAGE FOR PLUVICTO[15,†]

>8 of 10

COVERED PATIENTS PAID $0 OUT-OF-POCKET PER INFUSION[16]

A review of claims data between Q1 2023 and 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.

~98% PRIOR AUTHORIZATION APPROVAL RATE[17,‡]

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

PA, prior authorization.

***This is not a guarantee of coverage. Patient out-of-pocket costs may vary. Coverage and reimbursement decisions vary.**

†Coverage determined based on patients treated with at least one ARPI. The other 20% do not have published policies and/or cases may be determined on an individual basis. Follow up with the patient's plan to determine coverage.[14]

‡Average PA approval rate for patients when enrolled through Novartis Patient Support.[16]

Please see Important Safety Information throughout and on pages 21-22 and full Prescribing Information.

PLUVICTO®
lutetium Lu 177 vipivotide tetraxetan
INJECTION FOR INTRAVENOUS USE

NOVARTIS PATIENT SUPPORT™ OFFERS A COMPREHENSIVE PROGRAM TO HELP ELIGIBLE PATIENTS START, STAY, AND SAVE ON PLUVICTO

Support tailored to referring providers and their patients:

1:1 Patient Navigation Support

Here to guide patients through the referral process, financial assistance, what to anticipate with treatment, and answers to common questions

Call **1-844-638-7222** Monday - Friday, 8:00 AM - 8:00 PM ET to speak to a Novartis Patient Navigator

Find a PLUVICTO Treatment Center and information about their referral process

Novartis Patient Support works with treatment centers to update this list frequently to include helpful details and newly certified locations available

Referring Provider Support

Scan QR code and fax Start Form to **1-844-638-7329** to enroll

Our dedicated Novartis Patient Support team can help you navigate the referral process

- Benefit investigations in less than 2 days
- Referral follow-up with treatment centers for enrolled patients

View the patient website coverage and support page

View the Treatment Center Locator

View the Start Form

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

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INDICATIONS AND IMPORTANT SAFETY INFORMATION

Indications

PLUVICTO® (lutetium Lu 177 vipivotide tetraxetan) is indicated in combination with androgen receptor pathway inhibitor (ARPI) therapy for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic androgen pathway modulation-naïve or -sensitive (mAPMN/S) prostate cancer.

PLUVICTO is indicated for the treatment of adult patients with PSMA-positive metastatic androgen pathway modulation-resistant (mAPMR) prostate cancer who have been treated with 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 others 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 room from others 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 clinical trials (PSMAddition, PSMAfore, VISION) grade 3 or 4 decreased hemoglobin (ranged from 4.3-15%), decreased leukocytes (4.4-7%), decreased neutrophils (3.5-4.5%), and decreased platelets (1.1-9%) occurred in patients treated with PLUVICTO. 5 myelosuppression-related deaths have occurred, including one due to bone marrow failure during long-term follow-up.
- 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 clinical trials grade 3 or 4 acute kidney injury (ranged from 1.3-3.4%) 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.

Please see full Prescribing Information.

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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 PSMAddition, PSMAfore and VISION studies (N=1320), the most common (≥20%) adverse reactions, including laboratory abnormalities, were decreased lymphocytes (86%), decreased hemoglobin (68%), fatigue (51%), dry mouth (46%), decreased neutrophils (35%), nausea (35%), decreased platelets (33%), decreased estimated glomerular filtration rate (28%), increased aspartate aminotransferase (25%), decreased sodium (22%), increased magnesium (22%), increased potassium (21%), decreased calcium (21%), and increased alkaline phosphatase (20%).

Please see full Prescribing Information.

References:

1. Pluvicto. Prescribing information. Novartis Pharmaceuticals Corp. **2.** Data on file. Pre-filled syringe information. Novartis Pharmaceuticals Corp; 2025. **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.** Data on file. PLUVICTO PSMAddition trial. Novartis Pharmaceuticals Corp; June 2026. **5.** 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 **6.** Data on file. Medical illustrations for treatment guide. Novartis Pharmaceuticals Corp; 2024. **7.** Occupational Safety and Health Administration. Ionizing radiation. https://www.osha.gov/ionizing-radiation/control-prevention. Accessed October 30, 2023. **8.** Occupational Safety and Health Administration. Guidelines for cytotoxic (antineoplastic) drugs. https://www.osha.gov/enforcement/directives/std-01-23-001. Accessed November 2, 2023. **9.** 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. **10.** 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 **11.** Data on file. PLUVICTO Prefilled Syringe Information. Novartis Pharmaceuticals Corp; 2024. **12.** Data on file. Radiation half lives. Novartis Pharmaceuticals Corp. **13.** Centers for Disease Control and Prevention. Radiation and your health: facts about radiation from air travel. https://www.cdc.gov/radiation-health/data-research/facts-stats/air-travel.html. Accessed December 16, 2024. **14.** Vico MA, Pellicer OJ, Lopez V, et al. Lutetium-177 on ambulatory basis, a radiation safety approach. *Radiat Phys and Chem*. 2024;223:111898. doi:10.1016/j.radphyschem.2024.111898 **15.** Data on file. MMIT Market Access Claims. June 2026. **16.** Data on file. PLUVICTO IQVIA LAAD data analysis. Novartis Pharmaceuticals Corp; Jan 2023 to Jun 2024. **17.** Data on file. PLUVICTO NPS Metrics. Novartis Pharmaceuticals Corp; Jan 2025 to Dec 2025.

TREATING PATIENTS WITH PLUVICTO

Learn more about how to monitor your patients with PSMA+ mAPMR PC (mCRPC) after only 1 ARPI 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 in mCRPC

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