PATIENT GUIDE

# PLUVICTO®▼

## (lutetium ($^{177}$Lu) vipivotide tetraxetan)

This guide has been created to provide information about PLUVICTO® to the patients who have been prescribed PLUVICTO® or their care givers.

Please refer to the Patient Information Leaflet for further information.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Pluvicto RMP EM vs2.0/FA-11534101/NOV 2025

PLUVICTO®
lutetium ($^{177}$Lu) vipivotide tetraxetan
FOR INJECTION

Dear Patient,

You and your health care team have decided to initiate PLUVICTO® therapy to help treat your prostate cancer.

This guide will provide you with information on PLUVICTO® as well as on what you need to know before, during and after the administration.

If you have questions that are not answered by this guide, please do not hesitate to consult your health care team for additional support.

## 1. What is PLUVICTO® and how does it work?

PLUVICTO® is a radiopharmaceutical therapy (radioactive drug) used to treat adults with progressive castration-resistant prostate cancer that has spread to other parts of the body (metastatic) and has already been treated with other cancer treatments.

PLUVICTO® is used if the prostate cancer cells have a protein on their surface called prostate-specific membrane antigen (PSMA). PLUVICTO® binds to PSMA found on the surface of the prostate cancer cells. Once bound, the radioactive substance in PLUVICTO®, lutetium-177, gives off radiation that causes the prostate cancer cells to die.

Your doctor will carry out tests to see if PSMA is present on the surface of the cancer cells. Your cancer is more likely to respond to treatment with PLUVICTO® if the test result is positive.

## How long does the treatment with PLUVICTO® last?

PLUVICTO® is given approximately every 6 weeks for up to a total of 6 doses.

## How is PLUVICTO® administered?

PLUVICTO® is administered directly into a vein.

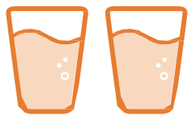
## 2. What do you need to know before, during, and after administration of PLUVICTO®?

**The use of PLUVICTO® involves exposure to radioactivity.**

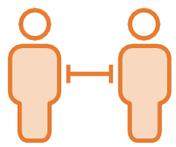
Your doctor and the nuclear medicine doctor have considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical outweighs the risk due to radiation.

Because this medicine is radioactive, you will have to follow the instructions described below to minimise radiation exposure to others unless otherwise instructed by your nuclear medicine doctor.

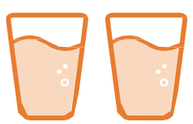
Your health care team will make sure that you are well prepared.



**Before administration of PLUVICTO®,** you should drink plenty of water so that you remain hydrated and urinate as often as possible during the first hours after administration.



**During the administration procedure,** you will be kept at a distance from other patients.



**After administration of PLUVICTO®,** you should drink plenty of water for 2 days so that you remain hydrated and urinate as often as possible to eliminate the radiopharmaceutical product from your body.



## SPECIFIC PRECAUTIONS AFTER ADMINISTRATION OF PLUVICTO®

Following general recommendations for patients can be considered along with national, local and institutional procedures and regulations.

**Contact with others, children, and/or pregnant women**

- Limit close contact (less than 1 metre) with:
  - others for 2 days.
  - children and pregnant women for 7 days.
- Sleep in a separate room from:
  - others for 3 days.
  - children for 7 days.
  - pregnant women for 15 days.
- Avoid sexual activity for 7 days.
- Do not father a child and do use a condom during intercourse throughout treatment with PLUVICTO®
  and for 14 weeks after your last dose.

## SPECIFIC PRECAUTIONS AFTER ADMINISTRATION OF PLUVICTO® (continued)

### Use of toilets

Take special precautions to avoid contamination for 2 days after administration:

- You must always sit when using the toilet.
- It is essential that you use toilet paper every time you use the toilet.
- Always wash your hands well after using the toilet.
- Flush all wipes and/or toilet paper down the toilet immediately after use.
- Flush any tissues or any other items that contain bodily waste, such as blood, urine and faeces, down the toilet. Items that cannot be flushed down the toilet, such as bandages, must be placed in separate plastic waste disposal bags (according to “Waste disposal recommendations” below).
- Any special medical equipment that could be contaminated by your bodily fluids (e.g., catheter bags, colostomy bags, bedpans, water nozzles) must be emptied immediately into the toilet and then cleaned.



## SPECIFIC PRECAUTIONS AFTER ADMINISTRATION OF PLUVICTO® (continued)

### Showering and laundry

- Take a shower every day for at least 7 days after administration.
- Wash your underwear, pyjamas, sheets and any clothes that contain sweat, blood or urine separately from the laundry of others, using a standard washing cycle. You do not need to use bleach and you do not need extra rinses.

### Care givers

For 2-3 days after administration:

- People who are confined to bed or have reduced mobility will preferably receive assistance from a care giver. It is recommended that when providing assistance in the bathroom, the care giver wears disposable gloves.
- Care givers who clean up vomit, blood, urine or faeces should wear plastic gloves, which should be disposed of in a separate plastic waste disposal bag (see “Waste disposal recommendations” below).

## SPECIFIC PRECAUTIONS AFTER ADMINISTRATION OF PLUVICTO® (continued)

### Waste disposal recommendations

- All items to be thrown away should be discarded in a separate plastic waste disposal bag to be used only for this purpose.
- Keep the plastic waste disposal bags separate from the other household waste and away from children and animals.
- A member of the hospital staff will tell you how and when to get rid of these waste disposal bags.

### Hospitalisation and emergency care

- If for any reason you require emergency medical assistance or are unexpectedly admitted to the hospital during the first 7 days after your treatment, you should inform the health care professionals about the name, date and dose of your radioactive treatment.



## SPECIFIC PRECAUTIONS AFTER ADMINISTRATION OF PLUVICTO® (continued)

### Other precautions

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

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Malta Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal and sent by post or email to;

**P:** Pharmacovigilance Section at Post-Licensing Directorate, Malta Medicines Authority, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann. SGN 3000.

**E:** postlicensing.medicinesauthority@gov.mt.

Healthcare Professionals may also report any adverse events associated with the use of Pluvicto® to Novartis Pharma Services Inc., Representative Office, Malta, by phone on +356 21222872, online on www.novartis.com/report or by e-mail at drug_safety.malta@novartis.com.

Marketing Authorization Holder: Novartis Europharm Limited, Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland. Local Representative: Novartis Pharma Services Inc., Representative Office Malta. Tel No.: +356 21222872

**For electronic copies of this Educational Material, please refer to the Malta Medicines Authority website -** http://www.medicinesauthority.gov.mt/rmm **- and download the required material with the latest date.**

## NOTES

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This educational material is a part of the conditions of the Marketing Authorisation

For more detailed guidance on **Pluvicto** please refer to the Summary of Product Characteristics (SmPC) available at https://www.ema.europa.eu/en/documents/product-information/pluvicto-epar-product-information_en.pdf