

Pluvicto® ▼ (lutetium [¹⁷⁷Lu] vipivotide tetraxetan) patient booklet

You have been prescribed Pluvicto® to help treat your prostate cancer. This booklet explains more about what to expect before, during and after your treatment.

This booklet is intended for adult patients in the United Kingdom who have been prescribed Pluvicto® for their prostate-specific membrane antigen-positive metastatic castration-resistant prostate cancer (PSMA-positive mCRPC), or for whom the prescribing decision has been made.

This booklet **does not replace the Patient Information Leaflet (PIL)** that comes with your medication, or advice from your healthcare team. **Always read the PIL before starting your treatment and use Pluvicto® exactly as your healthcare team has described.**

This booklet has been developed and funded by Novartis Pharmaceuticals UK Limited.

Reporting side effects

If you get side-effects with any medication you are taking, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the information leaflet that comes in the pack.

▼ The medicine referred to in this material is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. Please see www.mhra.gov.uk/yellowcard for instructions on how to report side effects.

Introduction

Pluvicto® is a radioactive medicine used to help treat a type of cancer called prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC). This booklet contains information about the type of treatment you are receiving, and what to expect during the treatment process.

The PIL that comes with your medicine also contains important information that you should read carefully and keep for future reference. Please ask your doctor for a copy of this PIL. As with any medicine, the more you know about how it works and what to expect, the more confident and prepared you feel when you start to receive it.

At the end of this booklet, there is a pull-out guidance sheet summarising the key information presented in this booklet. This page can be torn out of the booklet and kept in a convenient place for you to refer to (e.g., on your fridge or a noticeboard).

A treatment card is also available to help keep a record of the dates of your treatment with Pluvicto®, along with a few helpful reminders for after your treatment. You can use this to refer back to, should you need to share information relating to your appointments with your family and friends, or other healthcare teams.

Ask your doctor if you have any further questions about prostate cancer or Pluvicto®.

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1

About Pluvicto[®] and prostate cancer



About Pluvicto® and prostate cancer

What is Pluvicto®?

Pluvicto® is a radioactive medicine that contains lutetium (¹⁷⁷Lu) vipivotide tetraxetan. It is used to help treat adults with an advanced type of prostate cancer that has spread to other parts of the body (metastatic) and has already been treated with other cancer treatments.¹

What type of prostate cancer is Pluvicto® used for?

Pluvicto® treats a type of cancer called prostate-specific membrane antigen-positive metastatic castration-resistant prostate cancer (PSMA-positive mCRPC).

- **mCRPC** is a type of prostate cancer that has spread to other parts of your body and is no longer responding to hormone treatment that lowers testosterone²
- **PSMA** is a protein that sits on the outside of prostate cancer cells and can be detected by a PSMA positron emission tomography scan. Over 80% of men with prostate cancer are PSMA-positive³⁻⁸

Why have I been prescribed Pluvicto®?

You and your doctor have decided to start Pluvicto® therapy as your mCRPC is PSMA-positive. This means your cancer can be targeted by Pluvicto®, wherever the cancer cells are in your body.¹

The use of Pluvicto® involves exposure to radioactivity. Your doctor will have carefully considered the benefits you may get from the treatment versus the risk due to radiation.¹

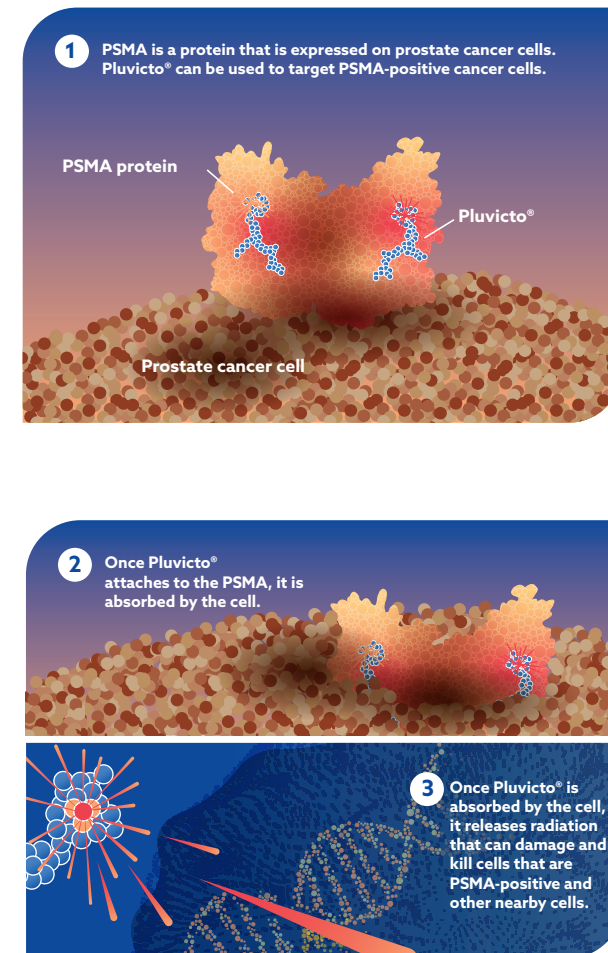
Although Pluvicto® is not a cure, treatment can help to reduce the risk of the cancer spreading, growing, or getting worse.⁹ Nevertheless, radiation exposure to you and your household contacts should be minimised during and after the treatment with Pluvicto®. Your doctor will make sure that you are well prepared.¹

How does Pluvicto® work?

Pluvicto® is a targeted medicine that binds to PSMA on the surface of the prostate cancer cells, wherever they are in the body. Once bound, it releases radiation that can damage and kill these PSMA-positive prostate cancer cells¹.



If you have any questions about how Pluvicto® can help treat your prostate cancer, please speak to your doctor.





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Being treated with Pluvicto[®]



Being treated with Pluvicto®

How will I be given Pluvicto®?

Pluvicto® is given by infusion into a vein. It is administered approximately every 6 weeks for a total of 6 doses.¹

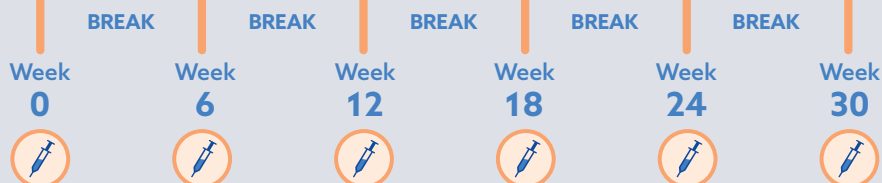


every
6 (± 1) weeks



6 doses

WITH 6 WEEKS BETWEEN TREATMENTS



Will I need any blood tests during treatment with Pluvicto®?

Your doctor will carry out blood tests before and during treatment to check your condition and to identify any side effects as early as possible. Based on the results, they may decide to delay, modify, or stop your treatment with Pluvicto®.¹

Where will I need to go to receive Pluvicto®?

You will need to go to the hospital to receive Pluvicto®. Your doctor will let you know where to go for your appointment. You will be kept at a safe distance from other patients during your treatment to help minimise their exposure to radiation.

What do I need to do before receiving Pluvicto®?

Prior to your treatment, drink plenty of water in order to urinate as often as possible during the first hours after treatment. Before you receive Pluvicto®, tell your doctor if any of these apply to you:¹

- You are allergic to lutetium (¹⁷⁷Lu) vipivotide tetraxetan or any of the other ingredients of this medicine
- You have been told that you have a low level of blood cell counts (haemoglobin, white blood cell count, absolute neutrophil count, platelet count) at a recent blood test
- You have or have had tiredness, weakness, pale skin, shortness of breath, bleeding or bruising more easily than normal or difficulty to stop bleeding, or frequent infections with signs such as fever, chills, sore throat, or mouth ulcers (possible signs of bone marrow suppression)
- You have or have had kidney problems
- You have or have had any other type of cancer or treatment for cancer as Pluvicto® contributes to your overall long-term cumulative radiation exposure
- You are sexually active, as:¹
 - All radiopharmaceuticals, including Pluvicto®, have the potential to cause harm to an unborn baby
 - You should not father a child and should use a condom for intercourse during treatment with Pluvicto® and for 14 weeks after your last dose
 - Pluvicto® may cause infertility

Follow all instructions given by your doctor carefully. They may differ from the general information contained in this booklet or the PIL.

What will happen during my appointment?

When you arrive at your appointment, your doctor will do some blood tests to make sure it is appropriate for you to receive Pluvicto®. You will be asked to **drink plenty of water** so that you remain hydrated and urinate as often as possible in the first few hours after administration.¹

Pluvicto® is administered directly into a vein. Your doctor will let you know how long administration should take and explain the administration set-up and process to you. If you have questions, please ask your doctor.¹



What should I do if I miss my appointment?

Please contact your doctor as soon as possible to reschedule your treatment.¹

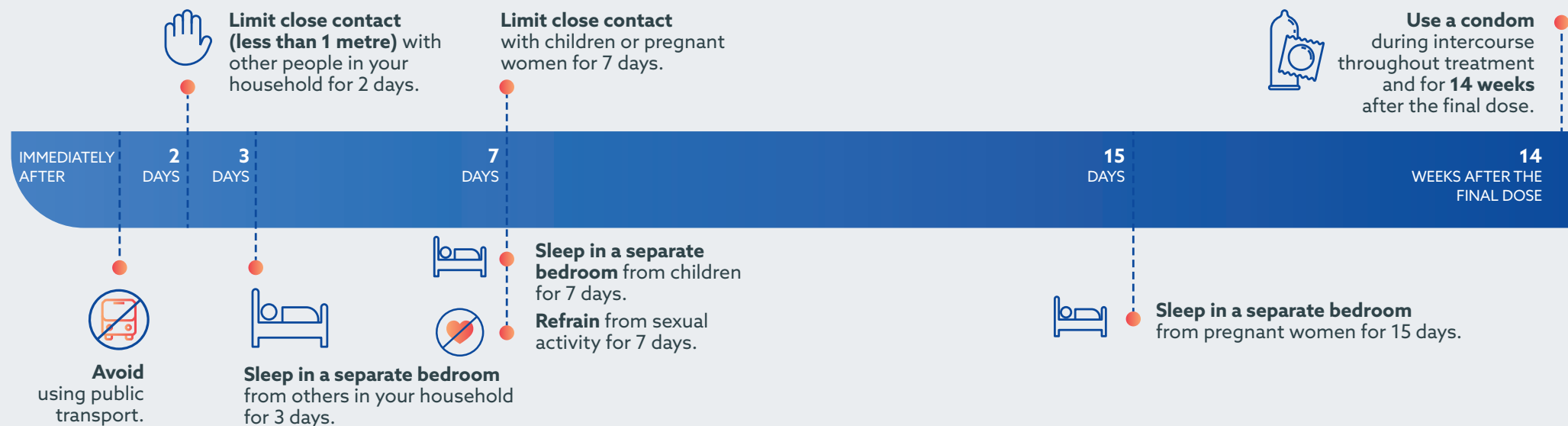
What do I need to do after my appointment?

After you have received Pluvicto®, **keep drinking plenty of water so that you remain hydrated and urinate as often as possible** to remove Pluvicto® from your body.¹⁰

Because it is a radioactive treatment, a small amount of the Pluvicto® you received may be transferred to others near you. Therefore, you will need to take some precautions to reduce radiation exposure to others after your treatment, unless otherwise instructed by your doctor.¹

Contact your healthcare team immediately if you experience symptoms such as fever, chills, sore throat, mouth ulcers, weakness, tiredness, pale skin, spontaneous bleeding or bruising, or shortness of breath, as this could be a sign of low blood cell levels. You should also inform your healthcare team of kidney problem symptoms such as passing urine less often than usual or passing much smaller amounts than usual.¹

Precautions to reduce radiation exposure to others:^{1,11}





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Important safety information



Important safety information

What are the most common side effects with Pluvicto®?

Like all medicines, Pluvicto® may cause side effects, although not everybody gets them. Pluvicto® may cause serious side effects, including:¹



Low level of blood cell counts. Tell your healthcare team right away if you develop any new or worsening symptoms, including:

- Tiredness or weakness
- Pale skin
- Shortness of breath
- Bleeding or bruising more easily than normal or difficulty stopping bleeding
- Frequent infections with signs such as fever, chills, sore throat, or mouth ulcers



Kidney problems. Tell your healthcare team right away if you develop any new or worsening symptoms, including passing urine less often or passing much smaller amounts of urine than usual.

If you experience any of the following serious side effects, tell your healthcare team right away.

Talk to your doctor about any side effects you experience during treatment with Pluvicto®. They may decide to temporarily delay your next dose, decrease your dose, or completely stop your Pluvicto® treatment if you develop certain serious side effects.¹

The most common side effects include:¹



Tiredness (fatigue)



Dry mouth



Nausea



Loss of appetite



Changes in bowel movements (constipation or diarrhoea)



Vomiting



Frequent urination with pain or burning sensation (urinary tract infection)



Abdominal pain



Weight loss

Please note that the side effects listed in this guide are not a full list of the known side effects. This guide should be read in conjunction with the Pluvicto® PIL.

If these side effects become severe, tell your doctor.

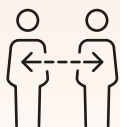
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Further information and guidance



Summary

- Pluvicto® is a targeted therapy that delivers radiation treatment directly to PSMA-positive prostate cancer cells, wherever they are in the body
- Pluvicto® can help to reduce the risk of the cancer spreading, growing, or getting worse
- Stay well hydrated before and after treatment with Pluvicto®
- Three important rules to reduce the risk of exposing others to radiation after treatment are:¹¹



Distance:
Keep a safe distance from others (>1 metre)



Hygiene:
Shower every day. Wash your hands often and well



Time:
Shorten the amount of time you spend close to others

- Talk to your doctor about any side effects you experience during treatment with Pluvicto®



Pluvicto® ▼ (lutetium [¹⁷⁷Lu]

vipivotide tetraxetan) patient guidance

We have created this pull-out guidance document so that you can take it to appointments or keep it in a place that makes most sense for you (i.e., sticking it on your fridge, or noticeboard).

Before my appointment

Tell your doctor if any of these apply to you:¹

- If you are allergic to lutetium (¹⁷⁷Lu) vipivotide tetraxetan or any of the other ingredients of this medicine
- You have low level of blood cell counts
- You have or have had tiredness, weakness, pale skin, shortness of breath, bleeding or bruising more easily than normal or difficulty to stop bleeding, or frequent infections with signs such as fever, chills, sore throat, or mouth ulcers
- You have or have had kidney problems
- You have or have had any other type of cancer or treatment for cancer
- You are sexually active

During my appointment

Drink plenty of water so that you remain hydrated.¹

After my appointment

- Drink plenty of water in the hours after treatment¹
- Do not use public transportation (such as a bus or train) right after your infusion appointment
- Limit close contact (less than 1 metre) with:
 - Household members for 2 days
 - Children and pregnant women for 7 days
- Sleep in a separate bedroom from others for 3 days after treatment, children for 7 days, and pregnant women for 15 days
- Refrain from sexual activity for 7 days and use a condom during treatment and for up to 14 weeks after the final dose of treatment
- Contact your doctor if you experience any side effects

Information on reporting adverse events can be found on the following page.



The most common side effects include:¹

- Tiredness (fatigue)
- Dry mouth
- Nausea
- Loss of appetite
- Changes in bowel movements (constipation or diarrhoea)
- Vomiting
- Frequent urination with pain or burning sensation (urinary tract infection)
- Abdominal pain
- Weight loss

Talk to your doctor about any side effects you experience during treatment with Pluvicto®. They may decide to temporarily delay your next dose, decrease your dose, or completely stop your Pluvicto® treatment if you develop certain serious side effects.¹

Your doctor will inform you if you need to take any additional special precautions after receiving this medicine, with regard to toilet use, showering, laundry, waste disposal, emergency medical assistance, unplanned hospitalisation, or travelling.¹ Please refer to the Pluvicto® patient booklet or the Pluvicto® Patient Information Leaflet (PIL) for further information.

Reporting side effects

If you get side-effects with any medication you are taking, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the information leaflet that comes in the pack.

▼ The medicine referred to in this material is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. Please see www.mhra.gov.uk/yellowcard for instructions on how to report side effects.

1. Pluvicto® Patient Information Leaflet (UK).
2. Memorial Sloan Kettering Cancer Center. About Your Pluvicto™ Treatment. Available from: <https://www.mskcc.org/cancer-care/patient-education/about-your-pluvicto-treatment>.

The information on this page is intended for patients who have been prescribed Pluvicto® (lutetium [¹⁷⁷Lu] vipivotide tetraxetan) for their prostate-specific membrane antigen-positive metastatic castration-resistant prostate cancer (PSMA positive mCRPC), or for whom the prescribing decision has been made.

Please note that the side effects listed in this guide are not a full list of the known side effects. This guide should be read in conjunction with the Pluvicto® PIL.

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Further information and guidance

- **Pluvicto® Patient Information Leaflet.**
Available from: <https://www.medicines.org.uk/emc/files/pil.13965.pdf>
- **Macmillan Cancer Support. Advanced Prostate Cancer.**
Available from: <https://www.macmillan.org.uk/cancer-information-and-support/prostate-cancer/advanced-prostate-cancer>
- **Prostate Cancer UK. Advanced prostate cancer.**
Available from: <https://prostatecanceruk.org/prostate-information-and-support/just-diagnosed/advanced-prostate-cancer>
- **Cancer Research UK. Metastatic prostate cancer.**
Available from: <https://www.cancerresearchuk.org/about-cancer/prostate-cancer/metastatic-cancer>

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11. Memorial Sloan Kettering Cancer Center. About Your Pluvicto™ Treatment. Available from: <https://www.mskcc.org/cancer-care/patient-education/about-your-pluvicto-treatment>.

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