PLUVICTO®▼

lutetium (^{177}Lu) vipivotide tetraxetan

1000 MBq/mL solution for injection/infusion

Please consult the Pluvicto Patient Information Leaflet (PIL) for full information

This brochure should only be given to patients in the Republic of Ireland, who have been prescribed Pluvicto® (lutetium [177Lu] vipivotide tetraxetan)

PLUVICTO®
Information for patients

This material has been developed and funded by Advanced Accelerator Applications, a Novartis company for patients who have been prescribed Pluvicto.

▼ This medicinal product is subject to additional monitoring. If you get any side effects, talk to your doctor, pharmacist or nurse. By reporting side effects, you can help provide more information on the safety of this medicine. You can report side effects directly to HPRA Pharmacovigilance, at www.hpra.ie. Side effects can also be reported to Novartis preferably at www.novartis.com/report, or by emailing drugsafety.dublin@novartis.com or by calling 01 2080 612.

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Dear Patient,

You and your nuclear medicine doctor have decided to initiate Pluvicto therapy to treat your prostate cancer now that it appears to be no longer responding well to your current treatment.

This brochure will provide you with information on Pluvicto as well as on what you need to know before and after its administration. Please consult the Pluvicto Patient Information Leaflet for full information. The Patient Information Leaflet may be provided with your medication or alternatively is available on www.medicines.ie.

This brochure does not replace the advice and care from your HCP team. If you have questions that are not answered by this brochure, please do not hesitate to consult your nuclear medicine doctor.

1. What is Pluvicto and how does it work?

What is Pluvicto?

Pluvicto is a radiopharmaceutical (radioactive drug) that is used to treat adults with a certain type of advanced prostate cancer that has spread to other parts of the body (metastatic) and has already been treated with other anti-cancer treatments.

For what type of cancer will Pluvicto be suitable?

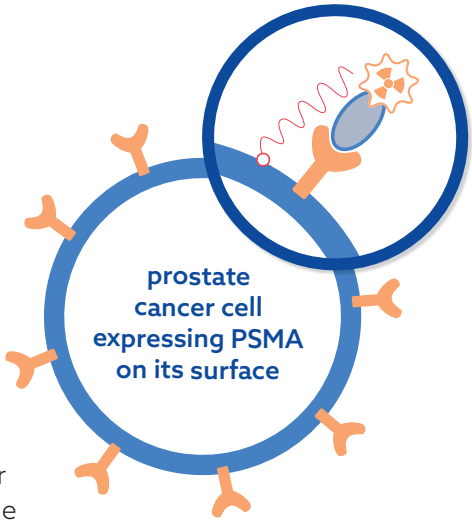
The type of prostate cancer which can be treated by Pluvicto is called PSMA-positive mCRPC.

PSMA (Prostate Specific Membrane Antigen) is a protein naturally found on the surface of prostate cells and is increased in prostate cancer cells.

mCRPC (Metastatic Castration Resistant Prostate Cancer) is a type of prostate cancer that has spread to other parts of the body (metastatic) for which hormone therapy is no longer effective in stopping or slowing the disease (castration resistant).

How does it work?

Pluvicto binds to a protein called PSMA that is found on the surface of prostate cancer cells. Once bound, the radiation emitted from the lutetium-177 causes the prostate cancer cells to die.



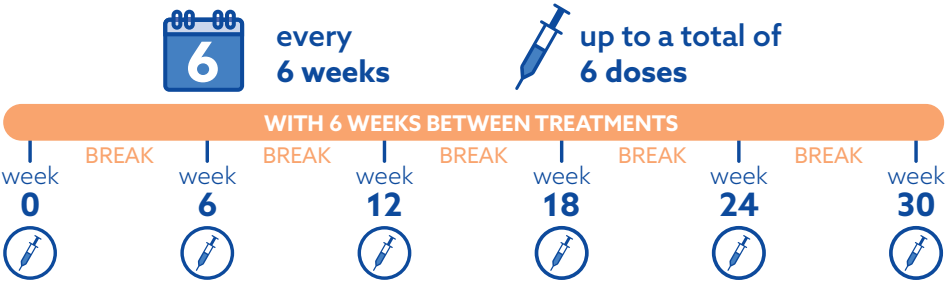
Tests will be performed to see if PSMA is present on the surface of the cancer cells. If the result is positive you may be eligible for treatment with Pluvicto.

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.

If you have any questions about how Pluvicto works or why this medicine has been prescribed for you, ask your nuclear medicine doctor.

2. What does the treatment with Pluvicto involve?

Pluvicto is administered as a combination with a specific type of hormone therapy. Pluvicto is administered directly into a vein as an injection or infusion of 7,400 MBq every 6 weeks (+/- 1 week) for a total of 6 doses, unless there is disease progression or unacceptable toxicity.



3. What will an appointment look like for the administration of Pluvicto?

You will need to see your nuclear medicine doctor in the hospital for the administration of Pluvicto. Ask your nuclear medicine doctor how and in which set up you will receive Pluvicto.

What kind of preparations are required for the administration of Pluvicto?

Your nuclear medicine doctor will do blood tests before and during treatment to check your condition and to detect any side effects as early as possible. Based on the results, your nuclear medicine doctor may decide to delay, modify or stop your treatment with Pluvicto if necessary.

You will be asked to drink plenty of water and urinate frequently, before and for two days after treatment to remove the product from your body after you have had the treatment.

Your nuclear medicine doctor will inform you about the usual duration of the procedure.

If you have questions about how long you will receive Pluvicto, talk to your nuclear medicine doctor.

4. Advice regarding risk from radiation exposure and general precautions to follow during daily activities

Remain hydrated and urinate frequently in order to eliminate the radiopharmaceutical product from your body

Limit close contact (less than 1 metre) with other people in the household for 2 days and with children or pregnant women for 7 days

Sleep in a separate bedroom for 3 days after treatment or in a bedroom separate from children for 7 days or pregnant women for 15 days

Contact your nuclear medicine doctor if you experience tiredness, weakness, pale skin, shortness of breath, bleeding or bruising more easily than normal or bleeding for longer than normal, or frequent infections with signs such as fever, chills, sore throat or mouth ulcers, which are possible signs of mylesuppression. This is a condition in which the bone marrow cannot make enough blood cells.

Refrain from sexual activity for 7 days. Do not father a child and do use condoms for intercourse during treatment and for 14 weeks after the final dose. Please note: Pluvicto may cause infertility. Please ask your nuclear medicine doctor how this may affect you, especially if you are planning to have children in the future. You may wish to seek advice on preservation of sperm before treatment starts

5. Specific precautions after administration of Pluvicto

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" on page 8).
- 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.

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 in your household, 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" on page 8).

5. 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.

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.

6. Are there any side effects I need to be aware of?

As with all medicines, Pluvicto may cause side effects, although not everybody gets them. Some side effects can be serious and others can be mild. If you experience any of the following serious side effects, **tell your nuclear medicine doctor right away**.

Very common side effects include:

- Tiredness, weakness, pale skin or shortness of breath which are possible signs of low red blood cell count, known as anaemia
- Bleeding or bruising more easily than normal or difficulty to stop bleeding which are possible signs of low platelets, a condition known as thrombocytopenia.
- Frequent infections with signs such as fever, sore throat or mouth ulcers which is a possible sign of low white blood cells, known as leukopenia or lymphopenia.

Common side effects include:

- Passing urine less often than usual or passing much smaller amounts of urine than usual are possible signs of a kidney problem known as acute kidney injury
- Tiredness, weakness, pale skin, shortness of breath, bleeding or bruising more easily than normal or difficulty to stop bleeding and frequent infections with signs such as fever, chills, sore throat or mouth ulcers (possible signs of low blood cell count, known as pancytopenia)

Other side effects include the following:

Very common:

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

Common:

- Swollen hands, ankles or feet (peripheral oedema)
- Dizziness
- Headache
- Disturbed sense of taste (dysgeusia)
- Fever (pyrexia)
- Dry eyes
- Dizziness, with a spinning sensation (vertigo)

If you get any side effects or if these side effects become severe, tell your nuclear medicine doctor immediately.

'Very common' means it may affect more than 1 in 10 people.

'Common' means may affect up to 1 in every 10 people.

Reporting side effects

This medicinal product is subject to additional monitoring. If you get any side effects, talk to your doctor, pharmacist or nurse. By reporting side effects, you can help provide more information on the safety of this medicine. You can report side effects directly to HPRA Pharmacovigilance, at **www.hpra.ie**. Side effects can also be reported to Novartis preferably at **www.novartis.com/report**, by emailing **drugsafety.dublin@novartis.com** or by calling **01 2080 612**.

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 Patient Information Leaflet (PIL).

Notes

Notes

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Advanced Accelerator Applications

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