Package leaflet: Information for the patient

Pluvicto® 1,000 MBq/mL solution for injection/infusion
lutetium (^{177}Lu) vipivotide tetraxetan

▼This medicine 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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your nuclear medicine doctor who will supervise the procedure.
- If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Pluvicto is and what it is used for

What Pluvicto is
Pluvicto contains lutetium (^{177}Lu) vipivotide tetraxetan. This medicine is a radiopharmaceutical product for therapy only.

What Pluvicto is used for
Pluvicto is used to treat adults with a certain type of advanced prostate cancer (called prostate-specific membrane antigen-positive metastatic castration-resistant prostate cancer [PSMA-positive mCRPC]) that is metastatic (this means it has spread to other parts of the body) and that has already been treated with other anti-cancer treatments.

How Pluvicto works
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. Your cancer is likely to respond to treatment with Pluvicto if the test result is positive.

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 you need to know before Pluvicto is used

Follow all instructions given by your nuclear medicine doctor carefully. They may differ from the general information contained in this leaflet.

Pluvicto must not be used
- if you are allergic to lutetium (^{177}Lu) vipivotide tetraxetan or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
If any of these apply to you, tell your nuclear medicine doctor before receiving Pluvicto:
- if you have low level of blood cell counts (haemoglobin, white blood cell count, absolute neutrophil count, platelet count)
- if 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 myelosuppression)
- if you have or have had kidney problems
- if 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

Before treatment with Pluvicto you should:
- drink plenty of water in order to urinate as often as possible during the first hours after treatment.

Children and adolescents
The safety and efficacy of this medicine have not been established in children and adolescents under 18 years of age.

Pregnancy, breast-feeding and fertility
The safety and efficacy of Pluvicto have not been established in females.

Before you receive Pluvicto, tell your nuclear medicine doctor if you are sexually active as:
- 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.

Driving and using machines
It is considered unlikely that Pluvicto will affect your ability to drive or use machines.

Pluvicto contains sodium
This medicine contains up to 88.75 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 4.4% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Pluvicto is used

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Pluvicto will only be used in special controlled areas. This radiopharmaceutical product will only be handled and given to you by people who are trained and qualified to use it safely. These persons will take special care for the safe use of this radiopharmaceutical product and will keep you informed of their actions.

The recommended dose is 7,400 MBq (megabecquerel, the unit used to express radioactivity). Pluvicto is given approximately every 6 weeks for a total of 6 doses.

Treatment with Pluvicto and conduct of the procedure
Pluvicto is administered directly into a vein.

Duration of the procedure
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.

Treatment monitoring
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.

After treatment with Pluvicto, you should:
- remain hydrated and urinate frequently in order to eliminate the radiopharmaceutical product from your body
- limit close contact (less than 1 meter) with others in your household for 2 days or with children and pregnant women for 7 days
- avoid sexual activity for 7 days
- sleep in a separate bedroom from others in your household for 3 days, from children for 7 days, or from pregnant women for 15 days

The nuclear medicine doctor will inform you if you need to take any special precautions after receiving this medicine. This may include special precautions for you or your caregiver with regard to toilet use, showering, laundry, waste disposal, emergency medical assistance, unplanned hospitalisation or travelling. Contact your nuclear medicine doctor if you have any questions.

If you have been given more Pluvicto than you should
An overdose is unlikely. However, in the event of an overdose, you will receive the appropriate treatment.

If you forget to receive Pluvicto
If you miss an appointment for treatment, contact your nuclear medicine doctor as soon as possible to reschedule.

Should you have any further questions on the use of Pluvicto, please ask the nuclear medicine doctor who supervises the procedure.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects could be serious
If you experience any of the following serious side effects, **tell your nuclear medicine doctor right away**.

Very common: may affect more than 1 in 10 people
- tiredness, weakness, pale skin or shortness of breath (possible signs of low level of red blood cells) (*anaemia*)
- bleeding or bruising more easily than normal or difficulty to stop bleeding and frequent infections with signs such as fever, sore throat or mouth ulcers (possible signs of low level of white blood cells) (*thrombocytopenia, leukopenia, lymphopenia*)

Common: may affect up to 1 in every 10 people
- passing urine less often than usual or passing much smaller amounts of urine than usual (possible sign of kidney problems) (*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 level of blood cells) (*pancytopenia*)

Other possible side effects
Other side effects include the following listed below. If these side effects become severe, tell your nuclear medicine doctor.

Very common: may affect more than 1 in 10 people
- tiredness (*fatigue*)
- dry mouth
- nausea
- loss of appetite
- changes in bowel movements (constipation or diarrhoea)
- vomiting
- urinary tract infection
- abdominal pain
- weight loss

Common: may affect up to 1 in every 10 people
- swollen hands, ankles or feet (*peripheral oedema*)
- dizziness
- headache
- disturbed sense of taste (*dysguesia*)
- fever (*pyrexia*)
- dry eye
- vertigo

Reporting of side effects
If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How Pluvicto is stored

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceuticals will be in accordance with national regulations on radioactive materials.

The following information is intended for the specialist only.
- Keep this medicine out of the sight and reach of children.
- Do not freeze.
- Store in the original package to protect from ionising radiation (lead shielding).
- Do not use Pluvicto after the expiry date and time which are stated on the label after EXP.
- Any unused medicinal product or waste material should be disposed of in accordance with local requirements

6. Contents of the pack and other information

What Pluvicto contains
- The active substance is lutetium (^{177}Lu) vipivotide tetraxetan. One mL of solution contains 1,000 MBq lutetium (^{177}Lu) vipivotide tetraxetan at the date and time of calibration.
- The other ingredients are: acetic acid, sodium acetate, gentisic acid, sodium ascorbate, pentetic acid, water for injections (see “Pluvicto contains sodium” in section 2).

What Pluvicto looks like and contents of the pack
Pluvicto is a clear, colourless to slightly yellow solution supplied in a clear, colourless type I glass vial, closed with a bromobutyl rubber stopper and aluminum seal.
Each vial contains a volume of solution that can range from 7.5 mL to 12.5 mL corresponding to a radioactivity of 7,400 MBq at the date and time of administration.
The vial is enclosed within a lead container for protective shielding.

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The following information is intended for healthcare professionals only:

The complete SmPC of Pluvicto is provided as a separate document in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical.

Please refer to the SmPC.