PLUVICTO®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your specialist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I being given PLUVICTO?

PLUVICTO contains the active ingredient lutetium (177Lu) vipivotide tetraxetan. PLUVICTO is used to treat prostate cancer in adults. For more information, see Section 1. Why am I being given PLUVICTO? in the full CMI.

2. What should I know before being given PLUVICTO?

Do not use if you have ever had an allergic reaction to lutetium (177Lu) vipivotide tetraxetan or any of the ingredients listed at the end of the CMI.

Talk to your specialist if you have any other medical conditions, take any other medicines, have household contacts, or you are planning to try for a baby or have an expecting partner.

For more information, see Section 2. What should I know before being given PLUVICTO? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PLUVICTO and affect how it works.

Refer to Section 3. What if I am taking other medicines? in the full CMI.

4. How do I receive PLUVICTO?

- PLUVICTO is given in a hospital or other licensed facility by specially trained staff.
- PLUVICTO is given once every 6 weeks into your vein for up to six doses.

More instructions can be found in Section 4. How do I receive PLUVICTO? in the full CMI.

5. What should I know while being given PLUVICTO?

Things you should do	• Attend your appointments every 6 weeks. • Follow advice from your specialist around decreasing radiation exposure to other persons during travel, hospital visits or at home. • Stay well hydrated and urinate frequently before and after you are given PLUVICTO. • Use a condom for sexual activity during treatment with PLUVICTO and for 14 weeks after your last dose.
Things you should not do	• Do not father a child while taking PLUVICTO.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how PLUVICTO affects you. PLUVICTO may make you feel tired.
Drinking alcohol	• Tell your specialist if you drink alcohol.
Looking after your medicine	• You will not need to store, handle, or dispose of this medicine. • The specialist needs to store PLUVICTO below 30°C (do not freeze) and to store in the original package to protect from ionising radiation (lead shielding).

For more information, see Section 5. What should I know while being given PLUVICTO? in the full CMI.

6. Are there any side effects?

Common side effects include: feeling tired, tummy pain, constipation, diarrhoea, urinary tract infection, headache, feeling sick, dizziness, dry mouth, trouble swallowing and/or heartburn, decreased appetite, weight loss, swollen hands, ankles or feet, dry eye, oral fungal infection, mouth sores, dry skin, vomiting. More serious side effects include: bruising more than normal, tiredness, weakness, pale skin, shortness of breath, passing less urine than normal, fever, chills, sore throat, or mouth ulcers. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

PLUVICTO (Ploo-VICK-toe)

Active ingredients: lutetium (177Lu) vipivotide tetraxetan

Consumer Medicine Information (CMI)

This leaflet provides important information about using PLUVICTO. **You should also speak to your specialist or pharmacist if you would like further information or if you have any concerns or questions about using PLUVICTO.**

Where to find information in this leaflet:

1. Why am I using PLUVICTO?
2. What should I know before I use PLUVICTO?
3. What if I am taking other medicines?
4. How will I receive PLUVICTO?
5. What should I know while using PLUVICTO?
6. Are there any side effects?
7. Product details

1. Why am I being given PLUVICTO?

PLUVICTO **contains the active ingredient** lutetium (177Lu) vipivotide tetraxetan. PLUVICTO contains a radioactive material that binds to a protein found in your prostate called prostate specific membrane antigen (PSMA). This will destroy cancer cells by delivering a controlled dose of radiation.

PLUVICTO is used to treat adults with a certain type of advanced prostate cancer (called metastatic castration-resistant prostate cancer) that has spread to other parts of the body (metastatic) and has already been treated with other cancer treatments. This type of cancer is a cancer of the prostate (a gland of the male reproductive system) that does not respond to treatment that decreases male hormones.

2. What should I know before being given PLUVICTO?

Warnings

Do not use PLUVICTO if:

- you are allergic to lutetium (177Lu) vipivotide tetraxetan, or any of the ingredients listed at the end of this leaflet.

Check with your specialist if you:

- are frequently sick with fever or chills.
- have or have had kidney problems.
- are pale, short of breath or bleeding/bruising more than normal.
- have or have had any other type of cancer or treatment for cancer, as PLUVICTO adds to your overall lifetime radiation exposure.
- have low levels of certain types of cells in the blood (red blood cells, white blood cells, neutrophils, and platelets).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

The safety and efficacy of this medicine have not been established in females.

PLUVICTO can cause harm to an unborn baby. You must limit extended close contact (less than one metre) with pregnant women for 7 days from receiving each dose of PLUVICTO to minimise radiation risk.

You must sleep in a separate bedroom from pregnant women for up to 15 days (see section: things you should do).

Contraception in males

You should avoid sexual activity for 7 days after administration of PLUVICTO.

You should not father a child and should use a condom for sexual activity during treatment with PLUVICTO and for 14 weeks after your last dose.

Ask your doctor or pharmacist for options of effective birth control.

Fertility

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 collecting and storing of sperm before treatment starts.

Children and adolescents

PLUVICTO has not been studied in children and adolescents under 18 years of age.

You must limit extended close contact (less than one metre) with children for 7 days from receiving each dose of PLUVICTO to minimise radiation risk.

PSMA test

Tests will be performed 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.

Treatment monitoring

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

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket, or health food shop.

Some medicines may interfere with PLUVICTO **and affect how it works.**

Check with your specialist, GP, or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PLUVICTO**.**

4. How do I receive PLUVICTO?

PLUVICTO is given once every 6 weeks into your vein for up to six doses. PLUVICTO is only given in a hospital or other licensed facility by specially trained staff.

How much will I receive

- The recommended dose is 7,400 MBq (megabecquerel, the unit used to measure radioactivity) given into your vein.

When to receive PLUVICTO

- You should receive a single dose of PLUVICTO once every 6 weeks, into your vein, for up to 6 doses (that is for up to 6 separate treatment visits).

Duration of treatment

- Your specialist will inform you about the usual length of the procedure.

If you miss an appointment to receive PLUVICTO

Contact your specialist as soon as possible to reschedule. You should receive PLUVICTO once every 6 weeks.

If you use too much PLUVICTO

PLUVICTO is given in a hospital or other licensed facility. It is unlikely that you will receive too much. Your specialist will check and treat you if you receive too much.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your specialist, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while being given PLUVICTO?

Things you should do

- drink plenty of water for 2 days so that you remain hydrated and urinate as often as possible during the first hours after you are given PLUVICTO.
- do not father a child and do use a condom during intercourse throughout treatment with PLUVICTO and for 14 weeks after your last dose.
- limit close contact (less than 1 meter) with others for 2 days or with children and pregnant women for 7 days from receiving each dose of PLUVICTO.
- avoid sexual activity for 7 days from receiving each dose of PLUVICTO.
- sleep in a separate room from others for 3 days, from children for 7 days, or from pregnant women for 15 days from receiving each dose 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.
- 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.

For 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.
- Caregivers who clean up vomit, blood, urine, or faeces should wear plastic gloves, which should be disposed of in a separate plastic waste disposal bag.

Household waste disposal

- 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 administration, you should inform the healthcare professionals about the name, date, and dose of your radioactive treatment.

Your specialist will inform you if you need to take any other special precautions after receiving this medicine. Contact your nuclear medicine doctor (your specialist) if you have any questions or are planning any travel.

Call your specialist straight away if you:

- are unable to pass urine when going to the toilet.
- feel short of breath or experience wheezing or swelling of the mouth, face and eyes.
- experience weakness, pale skin, 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 (bone marrow failure).

Remind any doctor, dentist, or pharmacist you visit that you are using PLUVICTO.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how PLUVICTO affects you. PLUVICTO may make you feel tired.

Drinking alcohol

Tell your specialist if you drink alcohol.

Looking after your medicine

You will not have to store or handle this medicine. This medicine will remain at the facility where your specialist treated you.

Getting rid of any unwanted medicine

PLUVICTO is only given in special facilities by appropriately qualified staff. They will be required to dispose of the medicine following treatment in accordance with special laws.

6. Are there any side effects?

All medicines can have side effects. Some side effects could be serious and may need medical attention.

See the information below and, if you need to, ask your specialist, GP, or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Tummy problems: • Tummy pain • Constipation/diarrhoea • Vomiting • Loss of appetite • Feeling sick • Trouble swallowing and/or heartburn **Kidney problems:** • Urinary tract infection (frequent urination with pain or burning sensation) **General well-being:** • Dizziness • Feeling tired • Dry mouth • Mouth sores • Weight loss • Headache • Dry skin • Oral fungal infection **Sensory problems:** • Dry eye • Changes to taste • Swelling of hands, ankles, or feet • Vertigo	**Speak to your specialist or GP if you have any of these less serious side effects and they worry you.** **If these side effects become severe, please tell your doctor, pharmacist, or healthcare provider.**

Serious side effects

Serious side effects	What to do
Signs of an allergic reaction: • feeling short of breath or experience wheezing or swelling of the mouth, face and eyes. **Blood problems:** • Feeling tired or weak • Pale skin, shortness of breath • Bleeding or bruising more than normal, difficulty to stop bleeding. • Frequent infections that include fever, sore throat, mouth ulcers or chills **Kidney problems:** • Passing urine less often or in much smaller amounts than usual (possible signs of kidney problems).	**Call your specialist straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your specialist or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

What PLUVICTO contains

Active ingredient (main ingredient)	lutetium (177Lu) vipivotide tetraxetan
Other ingredients (inactive ingredients)	Acetic acid Sodium acetate Gentisic acid Sodium ascorbate Pentetic acid Water for injections

PLUVICTO 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.

PLUVICTO is given to you in your vein ('intravenously') at a hospital or other facility by appropriately trained staff. Do not receive PLUVICTO if you are allergic to any of these ingredients.

What PLUVICTO looks like

PLUVICTO is supplied in a glass vial, closed with a stopper and a seal. The vial is enclosed within a lead container for protective shielding. The amount in the vial can range from 7.5 mL to 12.5 mL to provide the required amount for your treatment. Your specialist will determine this.

1000 MBq/mL, vial with lead shield: Aust R 410282.

Who distributes PLUVICTO

PLUVICTO is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

Level 25, Victoria Cross Tower

155 Miller Street

North Sydney NSW 2060

Website: www.novartis.com.au

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