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Vipivotide Tetraxetan

Also called: Pluvicto; Lutetium Lu 177 vipivotide tetraxetan; 177Lu-PSMA-617; PSMA-617

What it is

The PSMA-targeted radioligand approved as Pluvicto (lutetium Lu 177 vipivotide tetraxetan) in March 2022 for PSMA-positive metastatic prostate cancer.

Approval status

FDA Approved. Approved in the US as Pluvicto (lutetium Lu 177 vipivotide tetraxetan), NDA 215833, on March 23, 2022 (Novartis); the label effective August 12, 2026 covers PSMA-positive metastatic prostate cancer that is androgen-pathway-resistant after ARPI therapy, and, with ARPI therapy, disease that is androgen-pathway-naive or -sensitive (Drugs@FDA via openFDA and the Pluvicto label, read October 3, 2026).

Dosing, as printed in the page's Recommended Dosing box

Manufacturer's recommended dosing (FDA label)

From the prescribing information. Other doses studied, if any, are in the full dosing data below.

Protocol and source	Dose	Frequency	Duration	Route
Label dose **[Approved label]** Pluvicto prescribing information, section 2 (DailyMed set 14908037, effective August 12, 2026)	7.4 GBq (200 mCi)	Every 6 weeks	Up to 6 doses, or until progression or unacceptable toxicity	Intravenous

Used in human trials

No manufacturer dose exists for this use: these are amounts given in published trials, not recommendations.

Protocol and source	Dose	Frequency	Duration	Route
VISION (2021) **[Human study]** PMID 34161051	7.4 GBq	Every 6 weeks	4 to 6 cycles	Intravenous

Educational information, not medical advice. Each dose above is tagged with its source: an approved label, a published human study, animal data, or amounts reported by users. None is a recommendation for you. An unapproved compound has no established safe or effective human dose, and products sold for "research use only" are not made or tested for people. Talk to a doctor before acting on anything on this site, including before you start, stop or change any medicine or dose.

Key human evidence

The first 3 of the 12 human studies carded on the page (12 study cards in all):

• **VISION phase 3, 831 men** (Human, 2021). In men with PSMA-positive metastatic castration-resistant prostate cancer after hormone tablets and chemotherapy, adding it to standard care extended median imaging-based progression-free survival from 3.4 to 8.7 months and overall survival from 11.3 to 15.3 months. Grade 3 or worse adverse events were more common (52.7% against 38.0%), but quality of life was not worsened. **PMID 34161051**

• **PSMAfore phase 3: before chemotherapy** (Human, 2024). In 468 chemotherapy-naive men who had progressed once on a hormone tablet, median radiographic progression-free survival was 9.3 months on lutetium-177 PSMA-617 against 5.6 months on a switch of hormone tablet. Grade 3 to 5 adverse events were less common, 36% against 48%. **PMID 39293462**

• **PSMAfore: final survival analysis** (Human, 2025). Median overall survival was 24.5 months against 23.1 months, not a significant difference; 60% of the comparison group crossed over to the drug, and adjusting for that gave a hazard ratio of 0.59. Dry mouth occurred in 59.5% and anaemia in 27.3%. **PMID 40680993**

Interactions

Human interaction studies found on PubMed (search of October 5, 2026):

• With various drugs, reviewed across 83 studies of therapeutic radiopharmaceuticals: interactions reported, most absent from product information and most at low evidence levels (88% CEBM level 3 or 4); the abstract does not list Pluvicto-specific pairs (PMID 41746558)

Side effects and cautions

Reported side effects	Contraindications and cautions
• Dry mouth, from uptake in the salivary glands • Fatigue and nausea • Anaemia and other low blood counts, monitored before each dose • More grade 3 or worse adverse events than hormonal therapy alone in PSMAddition (51% against 43%)	• Risk from radiation exposure: precautions for patients, caregivers and staff • Myelosuppression • Renal toxicity • Embryo-fetal toxicity • Infertility

Five questions to ask

1. Is Vipivotide Tetraxetan right for me, and is the labelled dose on this sheet right for my weight, age, kidney and liver function?
2. Here are the medicines and supplements I take. Do any of them interact with Vipivotide Tetraxetan? This sheet lists the interactions on record.
3. Which side effects should make me stop and call you, for example dry mouth?
4. Do any of the cautions on this sheet apply to me, such as: Risk from radiation exposure: precautions for patients, caregivers and staff?
5. What should we check before I start and while I am on it (blood tests, blood pressure, weight), and how often?

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