



Papzimeos™

zopapogene imadenovec-drba
For subcutaneous injection 5 x 10¹¹ PU/mL

The first and only FDA-approved therapy to treat recurrent respiratory papillomatosis (RRP) in adults.^{1,2}

INDICATION

PAPZIMEOS is a non-replicating adenoviral vector-based immunotherapy indicated for the treatment of recurrent respiratory papillomatosis in adults.

Important Safety Information

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Injection-Site Reactions: Injection-site reactions have occurred with PAPZIMEOS injection. Monitor patients for local site reactions for at least 30 minutes after the initial treatment.

Thrombotic Events: Thrombotic events may occur following administration of adenoviral vector-based therapies. Monitor patients for signs and symptoms of thrombotic events and treat events according to clinical practice.

ADVERSE REACTIONS

The most commonly reported adverse reactions (≥5% of patients) in PAPZIMEOS-treated patients were injection site reactions, fatigue, chills, pyrexia, myalgia, nausea, headache, tachycardia, diarrhea, vomiting, and hyperhidrosis.

USE IN SPECIFIC POPULATIONS

Pregnancy: There are no available data with PAPZIMEOS in pregnant women.

Lactation: There is no information available on the presence of PAPZIMEOS in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for PAPZIMEOS and any potential adverse effects on the breastfed child from PAPZIMEOS or from the underlying maternal condition.

Pediatric Use: The safety and effectiveness of PAPZIMEOS have not been established in pediatric patients.

Geriatric Use: Clinical studies of PAPZIMEOS did not include sufficient numbers of patients 65 years of age and older to determine whether they respond differently from younger patients.

To report SUSPECTED ADVERSE REACTIONS, contact Precigen, Inc. at 1-855-PGE-NRRP (1-855-743-6777) or medinfo@precigen.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information for complete information on Dosage and Administration.

PAPZIMEOS dosing & administration

PAPZIMEOS is for subcutaneous injection provided as a suspension in a single-dose vial¹

The recommended dose of PAPZIMEOS is 5×10^{11} PUs per injection administered as a subcutaneous injection four times over a 12-week interval.¹



*Prior to the initial administration of PAPZIMEOS, perform a surgical debulking of visible papilloma to establish minimal residual disease.¹

[†]The second administration should occur no less than 11 days after the initial administration.¹

[†]To maintain minimal residual disease during treatment with PAPZIMEOS, remove visible papilloma, if present, prior to the third and fourth administration of PAPZIMEOS.¹

✓ PAPZIMEOS carton should be stored in an appropriate freezer at $\leq -60^{\circ}\text{C}$ [$\leq -76^{\circ}\text{F}$] until ready to thaw and administer.¹

✓ PAPZIMEOS MUST BE RAPIDLY thawed before use and prepared for immediate administration.¹

✓ Once thawed, DO NOT place the PAPZIMEOS vial in a refrigerator, freezer, or on dry ice. Protect PAPZIMEOS from light. DO NOT shake the vial.¹

✓ DO NOT hold PAPZIMEOS at room temperature for more than 60 minutes after thawing.¹

PU=particle unit.

References: 1. PAPZIMEOS. Package insert. Precigen, Inc; 2025. 2. Norberg SM, Valdez J, Napier S, et al. PRGN-2012 gene therapy in adults with recurrent respiratory papillomatosis: a pivotal phase 1/2 clinical trial. *Lancet Respir Med.* 2025;13(4):318-326. doi:10.1016/S2213-2600(24)00368-0

Select Important Safety Information

INDICATION

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Important Safety Information

CONTRAINDICATIONS

None.

Receiving PAPZIMEOS¹

PAPZIMEOS carton is shipped frozen at $\leq -60^{\circ}\text{C}$ [$\leq -76^{\circ}\text{F}$] in an insulated shipping box containing dry ice. On receipt, PAPZIMEOS carton must be stored in a freezer at $\leq -60^{\circ}\text{C}$ [$\leq -76^{\circ}\text{F}$].

Preparation and handling¹

- PAPZIMEOS is provided as a single-dose vial of sterile frozen suspension
- PAPZIMEOS MUST BE RAPIDLY thawed before use and prepared for immediate administration
- PAPZIMEOS should not be held at room temperature for more than 60 minutes after thawing
- Once thawed, DO NOT place PAPZIMEOS vial in a refrigerator, freezer, or on dry ice
- Protect PAPZIMEOS from light. DO NOT shake the vial
- Follow universal biosafety precautions for handling

Recommended supplies and materials¹

1. Freezer for storage of PAPZIMEOS at temperature $\leq -60^{\circ}\text{C}$ [$\leq -76^{\circ}\text{F}$]
2. Water bath or dry bead bath
3. 3 mL sterile syringe
4. Sterile needle (18 to 22 gauge without a filter) to withdraw PAPZIMEOS from the vial
5. Sterile needle for subcutaneous injection (23 to 25 gauge needle, 1/2- to 5/8-inch long)
6. 70% isopropyl alcohol pads

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Preparing PAPZIMEOS for injection¹

1. Remove the carton of PAPZIMEOS from the freezer when ready for administration.
2. Take the vial out of the pouch and immediately thaw in a 37°C [98.6°F] water bath or dry bead bath with the vial in an upright position until there are no visible ice crystals in the vial. Exposure of the thawed vial to the 37°C [98.6°F] water bath or dry bead bath should be less than or equal to 5 minutes.
3. Immediately after thawing, wipe the vial with 70% isopropyl alcohol or equivalent. Flip off the cap and wipe the rubber stopper top.
4. Visually inspect the vial. PAPZIMEOS should appear as a clear to slightly opalescent, colorless liquid, and free of visible particulates. DO NOT use if particulates or discoloration are visible in the suspension.
5. Aseptically withdraw 1 mL of PAPZIMEOS from the thawed vial using a 3 mL syringe with the 18 to 22 gauge needle. DO NOT use a filter needle.
6. Replace the 18 to 22 gauge needle with a subcutaneous injection needle (23 to 25 gauge).
7. Dispose of the used needle and empty vial in a biohazard container.

Also important:

- Do not store thawed PAPZIMEOS vials or filled syringes in a refrigerator, freezer, or on dry ice
- Treat any PAPZIMEOS spills with a virucidal agent (such as sodium hypochlorite with 0.5% or 6% hydrogen peroxide) for 15 minutes. Dispose of any unused product or waste materials as per facility biohazard waste disposal procedure

Administering PAPZIMEOS¹

When administering PAPZIMEOS via subcutaneous injection:

1. Select the lateral regions of the upper arm and thigh for injection. Avoid areas of edema, potential infection, wounds, scars or site of a recent subcutaneous injection.
2. Clean the site of injection thoroughly with an alcohol swab and allow at least 30 seconds to dry.
3. Inject PAPZIMEOS by inserting the needle at an angle to ensure delivery in the subcutaneous space.
4. Clean the area with an alcohol swab again, DO NOT massage the site of injection.
5. Place potentially contaminated materials from the injection site, including dressings, that may have the patient's bodily fluid/waste, in a sealable bag and dispose into regular trash. These precautions should be followed for 1-2 weeks after injection. Practice proper hand hygiene, such as hand washing, when coming into direct contact with patient body waste.
6. Avoid direct contact with the injection site (e.g., touching or scratching) and dressings for approximately 24 hours following treatment.