Papzimeos™

zopapogene imadenovec-drba

For subcutaneous injection 5 x 10^{11} PU/mL

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

NOW APPROVED

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.

Please see additional Important Safety Information on page 6 and full Prescribing Information.

STUDY DESIGN AND EFFICACY

PAPZIMEOS is a non-replicating adenoviral vector-based immunotherapy[1]

PAPZIMEOS was evaluated in an open-label, single-arm study of 38 adult patients with RRP in the United States. 35/38 patients received the recommended dosage of 5×10^{11} PU per injection.[1,2]

Primary endpoint: complete response

51% COMPLETE RESPONSE RATE at 1 year

(n=18/35) of patients treated with PAPZIMEOS required **no surgical intervention** for 1 year post treatment (95% CI: 34%-69%).[1]

Durability of complete response

15/18

15 out of 18 patients evaluated at 2 years demonstrated **continued complete response**.[1]

PU=particle units.

Select Important Safety Information

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.

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ADVERSE REACTIONS

Safety profile of PAPZIMEOS treatment[1]

Adverse reactions (ARs) occurring in ≥5% of patients treated with PAPZIMEOS (N=38)

Preferred Term	Grade 1-2* n (%)
Injection site reaction	37 (97)
Fatigue	28 (74)
Chills	25 (66)
Pyrexia	24 (63)
Myalgia	11 (29)
Nausea	10 (26)
Headache	4 (11)
Tachycardia	3 (8)
Diarrhea	2 (5)
Vomiting	2 (5)
Hyperhidrosis	2 (5)

*Graded per NCI CTCAE v5.0. There were no Grade >2 adverse reactions.[1]
NCI CTCAE=National Cancer Institute Common Terminology Criteria for Adverse Events.

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.

Other clinically significant adverse reactions occurring in <5% of patients included vision blurred (3%), injection site bruising (3%), dizziness (3%), dyspnea (3%), and pruritus (3%).[1]

Contact your Precigen Representative or call (866) 827-8180 Monday to Friday, 8 AM to 8 PM ET for more information.

Select Important Safety Information

USE IN SPECIFIC POPULATIONS

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

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PAPZIMEOS dosing & administration

PAPZIMEOS is for subcutaneous injection only. PAPZIMEOS is provided as a single-dose vial of sterile frozen suspension.[1]

The recommended dosage of PAPZIMEOS is 5×10^{11} particle units (PU) 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 ≤ -60°C [≤ -76°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]

Please see full Prescribing Information for complete information on DOSAGE AND ADMINISTRATION.

Select Important Safety Information

USE IN SPECIFIC POPULATIONS (cont'd)

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.

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Papzimeos SUPPORT

Precigen is committed to providing support to patients and HCPs for PAPZIMEOS. As part of this commitment, Papzimeos SUPPORT can provide information to help you understand the administrative aspects of the access and reimbursement process.

The information will feature an overview of the access process, including:

- Benefits Investigation
- Medical Exceptions and Sample Letter of Medical Necessity
- Prior Authorization (PA)
- Appeals

Commercial and government insurers all have different coverage and payment policies for medications and services. Check directly with the patient's insurer(s) to verify specific requirements for PAPZIMEOS.

Papzimeos SUPPORT can help support your patients and care team at any site of care throughout the access process. Download the enrollment form at PapzimeosSUPPORT.com. For questions or support, call (866) 827-8180, Monday to Friday, 8 AM to 8 PM ET.

Select Important Safety Information

USE IN SPECIFIC POPULATIONS (cont'd)

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

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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.

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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

Please see full Prescribing Information.

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