Product Monograph

Including Patient Medication Information

[Pr]PEN-VK

Penicillin V Potassium (Phenoxymethylpenicillin Potassium)

Tablets

For Oral use

480,000 i.u. (300 mg)

USP

Antibiotic

AA PHARMA INC.
1165 Creditstone Road, Unit #1
Vaughan, Ontario
L4K 4N7

Date of Authorization:
August 1, 2025

Control Number: 295711

Recent Major Label Changes

None at time of the most recent authorization	

Table of Contents

Certain sections or subsections that are not applicable at the time of the preparation of the most recent authorized product monograph are not listed.

Part 1: Healthcare Professional Information

1. Indications

PEN-VK (Penicillin V Potassium (Phenoxymethylpenicillin Potassium)) is indicated for:

- Mild to moderately severe infections caused by penicillin V sensitive microorganisms including streptococcal pharyngitis, staphylococcal infection without bacteremia and pneumococcal infections. Therapy should be guided by bacteriologic sensitivity tests and clinical response.

  Severe pneumonia, empyema, bacteremia, pericarditis, meningitis, and arthritis should not be treated with potassium phenoxymethyl penicillin during the acute stage.

  Indicated surgical procedures should be performed.

The following infections will usually respond to adequate dosage of potassium phenoxymethyl penicillin:

- **Streptococcal infections (without bacteremia):** Mild to moderate infections of the upper respiratory tract, scarlet fever, and mild erysipelas.

  Note: Streptococci in groups A, C, G, H, L, and M are very sensitive to penicillin. Other groups, including group D (enterococcus), are resistant.

- **Pneumococcal infections:** Mild to moderately severe infections of the respiratory tract.

- **Staphylococcal infections sensitive to penicillin V:** Mild infections of the skin and soft tissues.

  Note: Reports indicate an increasing number of strains of staphylococci resistant to penicillin V, which emphasizes the need for culture and sensitivity studies in treating suspected staphylococcal infections.

- **Fusospirochetosis (Vincent's Gingivitis and Pharyngitis):** Mild to moderately severe infections of the oropharynx usually respond to therapy with oral penicillin.

  Note: Necessary dental care should be accomplished in infections involving the gum tissue.

- For prophylaxis following rheumatic fever and/or chorea (Prophylaxis with oral penicillin on a continuing basis has proved effective in preventing recurrences of these conditions).

- To prevent bacterial endocarditis in patients with congenital and/or rheumatic heart lesions before dental procedures, minor upper respiratory tract surgery or instrumentation. Prophylaxis should be instituted the day of the procedure and continued for 2 or more postoperative days. Patients with a past history of rheumatic fever who are receiving continuous antibiotic prophylaxis may harbour increased numbers of penicillin resistant organisms; use of another anti-infective agent should be considered. If penicillin is to be used in these patients during surgery, the regular rheumatic fever program should be interrupted 1 week before the procedure. At the time of surgery, penicillin may be reinstituted prophylactically.

- For the prevention of bacteremia following tooth extraction.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of PEN-VK and other antibacterial drugs, PEN-VK should be used only to treat infections that are proven or strongly suspected to be caused by bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

1.1. Pediatrics

Pediatrics (< 12 years of age): Based on the data submitted and reviewed by Health Canada, the safety and efficacy of PEN-VK in pediatric patients has been established. Therefore, Health Canada has authorized an indication for pediatric use (See 4.2 Recommended Dose and Dosage Adjustment).

1.2. Geriatrics

Geriatrics: No data specific to this population are available to Health Canada.

2. Contraindications

PEN-VK is contraindicated in:

- patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a complete listing, see 6 Dosage Forms, Strengths, Composition, and Packaging.
- adjunctive prophylaxis for genitourinary instrumentation or surgery, lower intestinal tract surgery, sigmoidoscopy and childbirth.
- patients with a history of penicillin or cephalosporin allergy; against beta lactamase (penicillinase) producing organisms.
- the active treatment of syphilis, subacute bacterial endocarditis, diphtheria, gas gangrene, or other severe infections due to penicillin susceptible organisms.

3. Serious Warnings and Precautions Box

- Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients receiving penicillin therapy. Cross-sensitivity between penicillin and cephalosporins has been documented. (See 7 Warnings and Precautions, Immune).

4. Dosage and Administration

4.2. Recommended Dose and Dosage Adjustment

- The dosage should be determined according to the sensitivity of the microorganisms, the severity of infection and the clinical response.
- The usual dosage recommendations for adults and children 12 years and over are:
    - Streptococcal infections: Mild to moderately severe infections of the upper respiratory tract, including scarlet fever and mild erysipelas: 200,000 to 500,000 units every 6 to 8 hours for 10 days.

      In streptococcal infections, therapy should be given for 10 days minimum. Cultures should be taken following treatment to assure eradication of streptococci.

    - Pneumococcal infections: Mild to moderately severe infections of the respiratory tract, including otitis media: 400,000 to 500,000 units every 6 hours until the patient has been afebrile for at least 2 days.

- Staphylococcal infections: Mild infections of skin and soft tissue (culture and sensitivity tests should be performed): 400,000 to 500,000 units every 6 to 8 hours.
- Fusospirochetosis (Vincent's Infection) of the oropharynx: Mild to moderately severe infections: 400,000 to 500,000 units every 6 to 8 hours.
- Prophylaxis in the following conditions: To prevent recurrence following rheumatic fever and/or chorea: 200,000 to 250,000 units twice daily on a continuing basis.
- To prevent bacterial endocarditis in patients with rheumatic or congenital heart lesions who are to undergo dental or upper respiratory tract surgery or instrumentation: 500,000 units the day of the procedure, and 500,000 units every 6 hours for 2 days.

- **Pediatrics:** For children under 12 years of age, dosage is calculated on the basis of body weight. Infants and small children: 25,000 to 90,000 units (15 to 50 mg)/kg in 3 to 6 divided doses.

4.5. Missed Dose

If the patient misses a dose, instruct the patient to take the dose as soon as they remember. If it is almost time for the next dose, inform the patient to skip the missed dose and continue the regular dosing schedule.

5. Overdose

Treatment: Anaphylactic shock: epinephrine 0.3 mL of 1:1000 solution given by the i.v. or i.m. route in repeated doses until relief of bronchospasm and hypotension has occurred or excessive tachycardia induced. Mild hypersensitivity reactions may respond to antihistamines.

For the most recent information in the management of a suspected drug overdose, contact your regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669).

6. Dosage Forms, Strengths, Composition, and Packaging

Table 1 – Dosage Forms, Strengths, and Composition

Route of Administration	Dosage Form/ Strength/Composition	Non-Medicinal Ingredients
Oral	Tablet 300 mg	colloidal silicon dioxide, croscarmellose sodium, D&C Yellow #10 aluminum lake 14-18%, hydroxypropyl cellulose, magnesium stearate, methylcellulose, polyethylene glycol, purified water, sunset yellow aluminum lake 40% and titanium dioxide.

Description

Each orange, round, biconvex, film coated tablet, scored and engraved "300" on one side, other side plain, containing penicillin V potassium equivalent to 480,000 i.u. (300 mg) penicillin V. Available in bottles of 100, 500 and 1,000 tablets.

7. Warnings and Precautions

See 3 Serious Warnings and Precautions Box.

General

Oral administration should not be relied on in patients with severe illness, with nausea, vomiting, gastric dilatation, cardiospasm, or intestinal hypermotility.

Occasional patients will not absorb therapeutic amounts of oral penicillin.

Immune

Penicillin should be used with caution in individuals with histories of allergies.

Careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins and other allergens. Cross sensitivity between penicillin and cephalosporins is well documented. Effective and safe skin tests which will predict an anaphylactic reaction are not generally available.

Respiratory

Penicillin should be used with caution in individuals with histories of asthma.

Sensitivity/resistance

Development of Drug Resistant Bacteria: Prescribing PEN-VK in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and risks the development of resistant organisms.

Prolonged use of antibiotics may promote overgrowth of nonsusceptible organisms, including fungi. Should superinfection occur, take appropriate measures.

Skin

Severe Cutaneous Adverse Reactions: Severe cutaneous adverse reactions (SCAR) such as acute generalized exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN) have been reported in association with beta-lactam treatment. When SCAR is suspected, PEN-VK should be discontinued and appropriate therapy and/or measures should be taken.

7.1. Special Populations

7.1.1. Pregnancy

This information is not available for this drug product.

7.1.2. Breastfeeding

This information is not available for this drug product.

7.1.3. Pediatrics

Based on the data submitted and reviewed by Health Canada, the safety and efficacy of PEN-VK in

pediatric patients has been established. Therefore, Health Canada has authorized an indication for pediatric use. See 1.1 Pediatrics and 4.2 Recommended Dose and Dosage Adjustment.

7.1.4. Geriatrics

This information is not available for this drug product.

8. Adverse Reactions

8.1. Adverse Reaction Overview

All degrees of hypersensitivity including fatal anaphylaxis have been reported.

The most common reactions to oral penicillin are;

Blood and lymphatic system disorders: Fever and eosinophilia may frequently be the only reactions observed. Hemolytic anemia, leucopenia, and thrombocytopenia may occur.

Gastrointestinal disorders: Nausea, vomiting, epigastric distress, diarrhea, and black hairy tongue.

Immune disorders: Reactions resembling serum sickness, including chills, fever, edema, and anaphylaxis.

Nervous system disorders: Neuropathy

Renal and urinary disorders: Nephropathy

Skin and subcutaneous tissue disorders: The hypersensitivity reactions are skin eruptions (maculopapular to exfoliative dermatitis), urticaria.

9. Drug Interactions

9.3. Drug-Behaviour Interactions

The interaction of PEN-VK with individual behavioural risks (e.g. cigarette smoking, cannabis use, and/or alcohol consumption) has not been studied.

9.4. Drug-Drug Interactions

Interactions with other drugs have not been established.

9.5. Drug-Food Interactions

Interactions with food have not been established.

9.6. Drug-Herb Interactions

Interactions with herbal products have not been established.

9.7. Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

10. Clinical Pharmacology

10.1. Mechanism of Action

This information is not available for this drug product.

10.2. Pharmacodynamics

This information is not available for this drug product.

10.3. Pharmacokinetics

This information is not available for this drug product.

Special populations and conditions

This information is not available for this drug product.

11. Storage, Stability, and Disposal

Store at room temperature 15°C - 30°C in a tightly closed container.

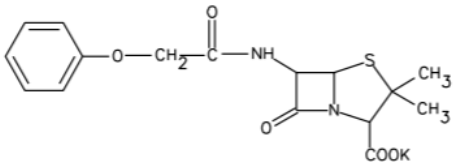
Part 2: Scientific Information

13. Pharmaceutical Information

Drug Substance

Non-proprietary name of the drug substance(s):	Phenoxymethylpenicillin Potassium.
Chemical name:	Potassium salt of (2S,5R,6R)-3,3-dimethyl-7-oxo-6-[(phenoxyacetyl)amino]-4-thia-1-azabicyclo [3.2.0]heptane-2-carboxylic acid
Molecular formula and molecular mass:	$C_{16}H_{17}KN_2O_5S$ and 388.5 g/mol

Structural formula:



Physicochemical properties:

Phenoxymethylpenicillin potassium is a white to almost white, crystalline powder / granules that is freely soluble in water, moderately soluble in ethanol and insoluble in chloroform, ether, fatty oil and liquid paraffin.

14. Clinical Trials

The clinical trial data on which the original indication was authorized is not available.

16. Non-Clinical Toxicology

This information is not available for this drug product.

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PrPEN-VK

Penicillin V Potassium Tablets

This Patient Medication Information is written for the person who will be taking **PEN-VK**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **PEN-VK**, talk to a healthcare professional.

Serious warnings and precautions box

- Serious and sometimes deadly allergic reactions have been reported in patients receiving penicillin therapy. Before starting therapy with PEN-VK, tell your healthcare professional about previous allergic reactions to penicillins, other antibiotics, or allergens.

What PEN-VK is used for:

PEN-VK is used to

- treat certain bacterial infections.
- prevent recurrence of rheumatic fever or chorea (an abnormal involuntary movement disorder).
- Prevent certain bacterial infections before or after some type of dental procedures or surgeries.

Antibacterial drugs like PEN-VK treat only bacterial infections. They do not treat viral infections.

How PEN-VK works:

PEN-VK works to:

- Stop growth of bacteria.
- Kill the bacteria.
- Reduce the infection in your body.

The ingredients in PEN-VK are:

Medicinal ingredient: Phenoxymethylpenicillin Potassium

Non-medicinal ingredients: colloidal silicon dioxide, croscarmellose sodium, D&C Yellow #10 aluminum lake 14-18%, hydroxypropyl cellulose, magnesium stearate, methylcellulose, polyethylene glycol, purified water, sunset yellow aluminum lake 40% and titanium dioxide.

PEN-VK comes in the following dosage form:

Tablets: 300 mg

Do not use PEN-VK if:

- You have ever had an allergic reaction to penicillin, other anti-biotics or any ingredients in this medicine.
- You have undergone any surgery and taking other antibiotics.
- You are currently taking an anti-biotic treatment for the following:
  - Syphilis;
  - Subacute bacterial endocarditis (a type of infection in the heart);
  - Diphtheria;
  - Gas gangrene;
  - Any other severe infections treated by penicillin.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PEN-VK. Talk about any health conditions or problems you may have, including if you:

- have allergies
- have asthma
- have severe illness with symptoms of nausea, vomiting or stomach / gut issues
- are pregnant, or planning to become pregnant
- are breast-feeding or plan to breast-feed

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take PEN-VK:

- Although you may feel better early in treatment, PEN-VK should be used exactly as directed.
- Misuse or overuse of PEN-VK could lead to the growth of bacteria that will not be killed by PEN-VK (resistance). This means that PEN-VK may not work for you in the future.
- Do not share your medicine.

Usual dose:

Adults and children 12 years or older:

Take PEN-VK exactly as directed by your healthcare professional. Your dose will depend on the type of infection that you have.

Children 12 years or younger:

Your healthcare professional will decide the dose based on your child's weight and infection.

Overdose:

If you think you, or a person you are caring for, have taken too much PEN-VK, contact a healthcare

professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

Do not take a double dose to make up for a forgotten dose. If you forget to take PEN-VK tablets, take the dose as soon as you remember and then take the next dose at the right time.

Possible side effects from using PEN-VK:

These are not all the possible side effects you may have when taking PEN-VK. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Nausea
- Vomiting
- Heartburn, bloating, and gas
- Diarrhea
- Black hairy tongue

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Unknown			
Blood Problems: • Eosinophilia (increased numbers of certain white blood cells): abdominal pain, rash, weight loss, wheezing • Hemolytic anemia (breakdown of red blood cells): pale skin, weakness, tiredness, shortness of breath, yellowing of your skin and/or the whites of your eyes, fever • Leucopenia (decrease in white blood cells): fever, chills, sore throat, faster heartbeat and breathing, other signs of infection • Thrombocytopenia (low blood platelet count): bruising or bleeding for longer than usual if you hurt yourself, fatigue and weakness • Fever			✓
Nervous System Problems • Neuropathy (damage to the nerves outside the spinal cord and the brain): numbness, weakness, or pain in the arms and legs			✓

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Kidney Problems: • Nephropathy (Kidney disease): weight loss and poor appetite; swollen ankles, feet or hands – as a result of water retention (oedema); shortness of breath; tiredness; blood in urine; an increased need to urination – particularly at night; difficulty sleeping; itchy skin			✓
Severe Allergic Reaction: • Anaphylaxis (sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing) • Itching, skin redness • Widespread scaling, peeling and flaking of the skin • Red raised skin rash Burning or prickling feeling on your skin • Flu like symptoms (chills, fever, swelling, joint pain and weakness)			✓
Severe Cutaneous Adverse Reactions (SCAR) (severe skin reactions that may also affect other organs): • Skin peeling, scaling, or blistering (with or without pus) which may also affect your eyes, mouth, nose or genitals, itching, severe rash, bumps under the skin, skin pain, skin color changes (redness, yellowing, purplish) • Swelling and redness of eyes or face • Flu-like feeling, fever, chills, body aches, swollen glands, cough • Shortness of breath, chest pain or discomfort			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at room temperature 15°C - 30°C in a tightly closed container.

Keep out of reach and sight of children.

If you want more information about PEN-VK:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (Drug Product Database: Access the database); the manufacturer's website https://www.aapharma.ca/en/our-product/; or by calling 1-877-998-9097.

This leaflet was prepared by AA Pharma Inc.

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