PRESCRIBING INFORMATION

PEN-VK

Penicillin V Potassium
(Potassium Phenoxymethyl Penicillin)

Antibiotic

Tablets USP
480,000 i.u. (300 mg)

AA PHARMA INC.
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INDICATIONS

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.

CONTRAINDICATIONS

Oral penicillin should not be used as adjunctive prophylaxis for genitourinary instrumentation or surgery, 1ower intestinal tract surgery, sigmoidoscopy and childbirth; in patients with a history of penicillin or cephalosporin allergy; against beta lactamase (penicillinase) producing organisms; the active treatment of syphilis, subacute bacterial endocarditis, diptheria, gas gangrene, or other severe infections due to penicillin susceptible organisms.

PRECAUTIONS

Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients receiving penicillin therapy.

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.

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**.**

Penicillin should be used with caution in individuals with histories of allergies and/or asthma.

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.

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

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

Susceptibility/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.

ADVERSE EFFECTS

All degrees of hypersensitivity including fatal anaphylaxis have been reported.

The most common reactions to oral penicillin are nausea, vomiting, epigastric distress, diarrhea, and balck hairy tongue. The hypersensitivity reactions are skin eruptions (maculopapular to exfoliative dermatitis), urticaria; reactions resembling serum sickness, including chills, fever, edema, and anaphylaxis. Fever and eosinophilia may frequently be the only reactions observed. Hemolytic anemia, leucopenia, thrombocytopenia, neuropathy, and nephropathy may occur.

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.

DOSAGE

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.

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.

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.

SUPPLIED

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.

In addition to potassium phenoxymethyl penicillin each tablet contains colloidal silicon dioxide, croscarmellose sodium, D&C Yellow #10 aluminum lake 14-18%, hydroxypropyl cellulose, magnesium stearate, methylcellulose, polyethylene glycol, FD&C yellow #6 aluminum lake and titanium dioxide.

STORAGE AND STABILITY

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

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

PEN-VK

Penicillin V Potassium
(Potassium Phenoxymethyl Penicillin)
Antibiotic Tablets USP
480,000 i.u. (300 mg)

Read this carefully before you start taking PEN-VK and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about PEN-VK.

What is PEN-VK used for?

- PEN-VK is used to treat infections that are caused by certain bacteria.

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

How does PEN-VK work?

PEN-VK works to:
- Stop growth of bacteria.
- Kill the bacteria.
- Reduce the infection in your body.

What are the ingredients in PEN-VK?
In addition to Potassium Phenoxymethyl Penicillin each tablet contains colloidal silicon dioxide, croscarmellose sodium, D&C Yellow #10 aluminum lake14-18%, hydroxypropyl cellulose, magnesium stearate, methylcellulose, polyethylene glycol, purified water, FD&C yellow #6 aluminum lake and titanium dioxide.

PEN-VK comes in the following dosage form:
PEN-VK 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.

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
- asthma
- severe illness with symptoms of nausea, vomiting or stomach / gut issues
- pregnant, or trying to become pregnant
- 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 doctor. Your dose will depend on the type of infection that you have.

Children 12 years or younger:
Your doctor will decide the dose based on your child's weight and infection.

Overdose:

If you think you have taken too much **PEN-VK**, contact your healthcare professional, hospital emergency department or regional poison control center immediately, even if there are no 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.

What are possible side effects from using PEN-VK?
- Nausea
- Vomiting
- Heartburn, bloating, and gas
- Diarrhea

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

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Severe Allergic Reaction: with symptoms such as: • 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			
Kidney Problems: • Kidney disease			✓
Blood Problems: • Anemia (illness resulting from the destruction of red blood cells) • Increase or decrease in some white blood cells • Low blood platelet count • Fever	✓		✓
Nervous System Problems • Numbness or weakness of the arms and legs		✓	
• Black hairy tongue	✓		

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to 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 (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health 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 to 30°C in a tightly closed container.

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 this patient medication information by visiting the Health Canada website (https://www.canada.ca/en/health-canada.html); the manufacturer's website http://www.aapharma.ca/products, or by calling 1-877-998-9097.

This leaflet was prepared by AA Pharma Inc.

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