PRESCRIBING INFORMATION

APO-PEN-VK

Penicillin V Potassium
(Potassium Phenoxymethyl Penicillin)

Tablets USP
500,000 i.u. (300 mg)

Antibiotic

Powder for suspension USP
500,000 i.u./5 Ml (300 mg/5 mL)

Powder for suspension USP
200,000 i.u./5 Ml (125 mg/5 mL)

Apotex Inc.
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Toronto, Ontario
M9L1T9

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Control No: 233619

PRESCRIBING INFORMATION

APO-PEN-VK

Penicillin V Potassium
(Potassium Phenoxymethyl Penicillin)

Antibiotic

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 APO-PEN-VK and other antibacterial drugs, APO-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, APO-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 APO-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 black 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, 500,000 units of i.m. aqueous penicillin G 1 hour before 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 Tablets: Each white tablet contains penicillin V potassium equivalent to 500,000 i.u. (300 mg) penicillin V. Available in bottles of 100, 500 and 1,000 tablets.

Powder For Suspension: After reconstitution, each 5 ml of pink, cherry flavored suspension contains penicillin V potassium equivalent to either 500,000 i .u. (300 mg) or 200,000 i.u. (125 mg) of penicillin V. Each strength is available in 60 and 100 ml bottles.

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

APO-PEN-VK

Penicillin V Potassium Powder for Oral Suspension, USP

Read this carefully before you start taking **APO-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 **APO-PEN-VK.**

What is APO-PEN-VK used for?

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

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

How does PEN-VK work?

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

What are the ingredients in APO-PEN-VK?

Medicinal ingredients: Penicillin V Potassium
Tablets:
D& C Yellow # 10 Aluminum Lake 14-18%, Sunset Yellow Aluminum Lake 40%, Methylcellulose 15 CPS, Magnesium Stearate, Croscarmellose Sodium, Colloidal Silicon Dioxide, Hydroxypropyl Cellulose Type LF, Polyethylene Glycol 8000, Titanium Dioxide, Purified Water

Oral Suspension
Non-medicinal ingredients: Cherry flavour, FDC Red #40, sodium benzoate, sodium citrate anhydrous, sodium cyclamate and sucrose

APO-PEN-VK comes in the following dosage forms:
Tablets, 300 mg
Powder for oral suspension, 125 mg/5 mL and 300 mg/5 mL

Do not use APO-PEN-VK if:
- You have ever had an allergic reaction to penicillin, other anti-biotics or any ingredients of this medicine.

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

- Although you may feel better early in treatment, APO-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 APO-PEN-VK (resistance). This means that APO-PEN-VK may not work for you in the future.
- Do not share your medicine.

Usual dose:

The recommended dose of penicillin for adults and children varies according to the infection being treated.
Many things can affect the dose of medication that a person needs, such as body weight and other medications. Please follow your doctor's recommended dose.

Overdose:

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

Missed Dose:

If you miss a dose, take it as soon as possible and continue with your regular schedule. If it is almost time for your next dose, skip the missed dose and continue with your regular dosing schedule. **Do not take a double dose to make up for a missed one.** If you are not sure what to do after missing a dose, contact your doctor or pharmacist for advice.

What are possible side effects from using APO-PEN-VK?

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

You may experience the following side effects:

- Nausea
- Vomitting
- Upset stomach
- Diarrhea
- Black hairy tongue
- Fever
- Chills

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	
Allergic Reaction – shortness of breath, rash, itching, hives, swelling of lips, face or tongue			✓
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, 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:
Tablets: Store at 15°C to 30°C.
Powder for suspension: Store at room temperature 15°C to 30°C.
Suspension: Store the oral suspension for 14 days under refrigeration.

If you want more information about APO-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 (http://hc-sc.gc.ca/index-eng.php); the manufacturer's website (http://www.apotex.ca/products), or by calling 1-800-667-4708.

This leaflet was prepared by Apotex Inc.

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