VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Phenoxymethylpenicillin (also known as penicillin V) is a β-lactam antibiotic, which works by inhibiting the ability of bacteria to synthesize cell walls. It is effective against a range of gram-positive bacteria that typically cause middle ear, nose and throat infections, lower respiratory tract infections, dental infections and skin and soft tissue infections e.g. scarlet fever and erysipelas (a type of skin infection). It is also used to prevent the recurrence of rheumatic fever. This natural penicillin is still the drug of choice for the treatment of group A streptococcal throat infections (pharyngitis) in patients who are not allergic to penicillin.

VI.2.2 Summary of treatment benefits

Phenoxymethylpenicillin potassium (Penicillin V or PenV) is a narrow spectrum antibiotic which is active against a selected group of bacterial types. It is narrow spectrum antibiotic used to treat mild to moderate infections caused by susceptible bacteria, i.e. bacteria that are not resistant to the antibiotic.

Penicillin has been the drug of choice for the treatment of a particular type of throat infection, group A ß-haemolytic streptococci pharyngitis, for more than four decades because it relieves symptoms faster and reduces the number of complications such as pus. Penicillin is also considered superior to its alternatives because of lack of resistance, fewer adverse effects , and lower costs (2).

Phenoxymethylpenicillin is safe and well-tolerated across indications, with few reported side effects or complications (adverse events (AEs)). Diarrhoea, nausea and exanthema (widespread rash) are the most frequent side effects.

VI.2.3 Unknowns relating to treatment benefits

None identified.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Hypersensitivity to penicillins	Phenoxymethylpenicillin potassium and/ or its excipients may cause hypersensitivity reactions in patients.	Primve is contraindicated in case of hypersensitivity to the active substance or to any of the excipients. These conditions should be closely monitored.
Diarrhoea/pseudomembranous colitis caused by Clostridium difficile	Antibiotic-associated diarrhoea is a well-recognized adverse reaction to oral penicillins.	To adjust the dosage according with the weight and follow the treatment duration indications. If you experience one or more of these side effects or any other undesirable effects, please inform your doctor or pharmacist.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Drugs interactions (methotrexate)	Simultaneous administration of phenoxymethylpenicillin potassium and *methotrexate* may require dose adjustment. Phenoxymethylpenicillin is an organic acid, which may inhibit the tubular secretion of methotrexate causing increased plasma concentrations Probenecid delays the renal excretion of penicillin, which can lead to higher serum concentrations of Primve for an extended period.
Use in patients with phenylketonuria	Granules for oral suspension contain aspartame, which is metabolised into phenylalanine. This is of importance in case of patients with phenylketonuria.
Use in patients with fructose intolerance	Granules for oral suspension contain fructose. Patients with the following rare hereditary condition should therefore not use the granules for oral suspension.

Missing information

Risk	What is known
Not applicable	

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in this documents as well as the prescription-only status are known as routine risk minimization measures which are considered sufficient for this medicinal product.

No additional risk minimization measures are proposed.

VI.2.6 Planned post authorisation development plan

Not applicable

VI.2.7 Summary of changes to the Risk Management Plan over time

Not applicable, first RMP or summary of changes.