

FORTIWIN-4

FORTIFIED PROCAINE PENICILLIN INJECTION I.M.

NAME OF THE MEDICINAL PRODUCT

Fortified Procaine Penicillin Sodium Injection

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains Procaine penicillin B.P. 3,000,000 I.U.(3g) and Benzylpenicillin sodium B.P. 1,000,000 I.U. (600mg)

PHARMACEUTICAL FORM

Powder for Solution for Injection

CLINICAL PARTICULARS

Therapeutic Indications

It has the same indications as penicillin. As its peak blood concentration is relatively low, it is only indicated in mild infections caused by penicillin-sensitive bacteria, such as tonsillitis, scarlet fever, crsipelas, furuncles and carbuncles. It is also effective for syphilis, Vincent's angina and gonorrhoea.

Posology and method of administration

It is given by i.m. injection only. A suitable amount of water for injection is added into the vial before use. 400,000 i.u. ~ 800,000 i.u. each time, once or twice a day.

Contraindications

A previous hypersensitivity reaction to any penicillin or to procaine is a contraindication.

Do not inject into or near an artery or nerve.

Special warnings and precautions for use

Before administration skin tests of procaine and penicillin should be made. It should not be administered to patients hypersensitive to penicillin and procaine.

The suspension prepared by adding a suitable amount of water for injection into the vial should be stored below 10°C and use up within 24 hours.

Whenever allergic reactions occur, penicillin should be withdrawn unless, in the opinion of the physician, the condition being treated is life-threatening and amenable only to penicillin therapy.

Do not inject intravenously or admix with other intravenous solutions.

Inadvertent intravascular administration, including inadvertent direct intra-arterial injection or injection immediately adjacent to arteries, has resulted in severe neurovascular damage, including transverse myelitis with permanent paralysis, gangrene requiring amputation of digits and more proximal portions of extremities, and necrosis and sloughing at and surrounding the injection site.

Severe effects and complications following accidental intravascular administration have most often occurred in infants and small children. Prompt consultation with an appropriate specialist is indicated if any evidence of compromise of the blood supply occurs at, proximal to, or distal to the site of injection.

Injection into or near a nerve may result in permanent neurological damage. Quadriceps femoris fibrosis and atrophy have been reported following repeated intramuscular injections of penicillin preparations into the anterolateral thigh.

Prolonged use of antibiotics may promote the overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, appropriate measures should be taken.

Interaction with other medicinal products and other forms of interaction

Tetracycline, a bacteriostatic antibiotic, may antagonize the bactericidal effect of penicillin, and concurrent use of these drugs should be avoided.

Concurrent administration of penicillin and probenecid increases and prolongs serum penicillin levels by decreasing the apparent volume of distribution and slowing the rate of excretion by competitively inhibiting renal tubular secretion of penicillin.

Pregnancy and lactation

Use in pregnancy

Procaine penicillin has been assigned to pregnancy category B by the FDA. Animal studies failed to reveal evidence of fetotoxicity or teratogenicity. Adverse effects have not been reported during human use; however, there are no controlled data in human pregnancies. Procaine penicillin is only recommended for use during pregnancy when benefit outweighs risk.

Use in lactation

Penicillin G is excreted into breast milk in low concentrations. Although no adverse effects were reported, three potential problems exist for the nursing infant: modification of bowel flora, direct effects on the infant (e.g., allergic response), and interference with the interpretation of culture results if a fever workup is required. It is recommended that caution be used when administering penicillin to nursing women.

Undesirable effects

There are three types of adverse reaction to procaine penicillin: severe allergic (anaphylaxis); faint (vaso-vagal); and non-allergic (pseudoanaphylactic). Similarities between these reactions can make diagnosis difficult. The clinical imperative is to exclude the life threatening anaphylactic reaction. A person who collapses from shock (low blood pressure and rapid weak pulse) or respiratory failure (from bronchospasm causing wheeze or angioedema causing respiratory obstruction) following an injection of procaine penicillin should

be treated for anaphylaxis. These severe allergic reactions are rare.

Overdose

If overdose is suspected, contact the local poison control center or emergency room immediately. Symptoms of overdose may include: seizures, confusion, mental/mood changes (e.g., agitation).

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

This preparation is available in the form of a sterile dry powder containing benzylpenicillin sodium (or potassium) and procaine penicillin with suitable amount of suspending and buffering agents. The advantage of such a preparation is that it can exert both the prompt action due to the high initial blood levels produced by the soluble sodium salt, and the prolonged action of the insoluble procaine penicillin salt which is absorbed and excreted slowly. Therefore, a single dose injection of this preparation can maintain an effective concentration in blood for 12-24 hours.

Pharmacokinetic properties

Penicillin G procaine is an equimolecular compound of procaine and penicillin G, administered intramuscularly as a suspension. It dissolves slowly at the site of injection, giving a plateau type of blood level at about 4 hours which falls slowly over a period of the next 15 to 20 hours.

Approximately 60% of penicillin G is bound to serum protein. The drug is distributed throughout the body tissues in widely varying amounts. Highest levels are found in the kidneys with lesser amounts in the liver, skin, and intestines. Penicillin G penetrates into all other tissues to a lesser degree with a very small level found in the cerebrospinal fluid. With normal kidney function, the drug is excreted rapidly by tubular excretion. In neonates and young infants and in individuals with impaired kidney functions, excretion is considerably delayed. Approximately 60 to 90 percent of a dose of parenteral penicillin G is excreted in the urine within 24 to 36 hours.

Preclinical safety data

No further information of relevance.

PHARMACEUTICAL PARTICULARS

List of excipients

None

Incompatibilities

It may be incompatible with other drugs, including a number of other antibacterials (e.g. tetracyclines, chloramphenicol, erythromycin, lincomycin). And it may be incompatible with metal ions and some rubber products. Its stability may be affected by ionic and nonionic surfactants, oxidising and reducing agents, alcohols, glycerol, glycols, macrogols and other hydroxy compounds, some paraffins and bases, some preservatives for example chlorocresol or thiomersal, carbohydrate solutions in an alkaline pH, fat emulsions, blood and blood products, and viscosity modifiers.

Shelf life

3 years.

Special precautions for storage

Store below 30°C and protect from light.

Keep out of reach of children.

Should not be used after 3 years of manufacturing.

Nature and contents of container

20 ml clear/transparent glass mould vial with butyl rubber stopper and three-joint aluminium cap, 50 vials in a cardboard box

Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Any residual solution should be discarded.

MARKETING AUTHORISATION HOLDER

ABACUS Pharma (Africa) Ltd

P.O. Box 12294, Dar Es Salaam, Tanzania

DISTRIBUTION CATEGORY

POM – Medicinal product subject to medical prescription

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Sep,2019

Manufactured in China by:
Reyoung Pharmaceutical Co., Ltd.
No.1 Ruiyang Road, Yiyuan County,
Shandong Province, P.R. China



Manufactured for:
Abacus Pharma (A) Limited
EAST AFRICA