1. Name of the Medicinal Product

1.1 (Invented) Name of The Medicinal Product

ROCAPEN

1.2 Strength

Each vial contains:

Procaine Penicillin (Sterile) BP 3gm

Benzyl Penicillin Sodium (Sterile) BP 600mg

1.3. Pharmaceutical Dosage Form

Parenteral Preparation (Dry Injection)

2. Qualitative And Quantitative Composition

Each vial contains:

Procaine Penicillin (Sterile) BP 3gm

Benzyl Penicillin Sodium (Sterile) BP 600mg

Water for Injections BP q.s.

3. Pharmaceutical Form

Dry Injection

4. Clinical Particulars

4.1 Therapeutic Indications

Rocapen is indicated for most wound infections, pyogenic infections of the skin, soft tissue infections and infections of the nose, throat, nasal sinuses, respiratory tract and middle ear, etc.

It is also indicated for the following infections caused by penicillin-sensitive microorganisms: Generalized infections, septicaemia and pyaemia from susceptible bacteria.

Acute and chronic osteomyelitis, sub-acute bacterial endocarditis and meningitis caused by susceptible organisms. Suspected meningococcal disease. Gas gangrene, tetanus, actinomycosis, anthrax, leptospirosis, rat-bite fever, listeriosis, severe Lyme disease, and prevention of neonatal group B streptococcal infections.

Complications secondary to gonorrhoea and syphilis (e.g. gonococcal arthritis or endocarditis, congenital syphilis and neurosyphilis). Diphtheria, brain abscesses and pasteurellosis.

4.2 Posology and Method of Administration

For I.M. Injection only.

Suspend in 8ml of water for injection Immediately before use.

Adults

600 to 3,600mg (1 to 6 mega units) daily, divided into 4 to 6 doses, depending on the indication. Higher doses (up to 14.4 g/day (24 mega units) in divided doses) may be given in serious infections such as adult meningitis by the intravenous route.

In bacterial endocarditis, 7.2 to 12 g (12 to 20 mega units) or more may be given daily in divided doses by the intravenous route, often by infusion.

Doses up to 43.2 g (72 mega units) per day may be necessary for patients with rapidly spreading gas gangrene.

High doses should be administered by intravenous injection or infusion, with intravenous doses in excess of 1.2g (2 mega units) being given slowly, taking at least one minute for each 300 mg (0.5 mega unit) to avoid high levels causing irritation of the central nervous system and/or electrolyte imbalance.

For the prevention of Group B Streptococcal disease of the newborn, a 3 g (5 mega units) loading dose should be given to the mother initially, followed by 1.5 g (2.5 mega units) every 4 hours until delivery.

Children aged 1 month to 12 years

100 mg/kg/day in 4 divided doses; not exceeding 4 g/day.

Or as directed by the physician.

4.3 Contraindications

Allergy to penicillins. Hypersensitivity to any ingredient of the preparation.

Cross allergy to other beta-lactams such as cephalosporins should be taken into account.

4.4 Special Warning and Precautions For Use

Fortified Procaine Penicillin can cause hypokalaemia and sometimes hypernatraemia. Use of a potassium-sparing diuretic may be helpful. In patients undergoing high-dose treatment for more than 5 days, electrolyte balance, blood counts and renal functions should be monitored.

In the presence of impaired renal function, large doses of Fortified Procaine Penicillin can cause cerebral irritation, convulsions and coma.

Skin sensitization may occur in persons handling the antibiotic and care should be taken to avoid contact with the substance.

It should be recognized that any patient with a history of allergy, especially to drugs, is more likely to develop a hypersensitivity reaction to penicillin. Patients should be observed for 30 minutes after administration and if an allergic reaction occurs the drug should be withdrawn and appropriate treatment given.

Delayed absorption from the intramuscular depot may occur in diabetics.

Prolonged use of Fortified Procaine Penicillin may occasionally result in an overgrowth of non-susceptible organisms or yeast and patients should be observed carefully for superinfections.

Pseudomembranous colitis should be considered in patients who develop severe and persistent diarrhoea during or after receiving Fortified Procaine Penicillin. In this situation, even if

Clostridium difficile is only suspected, administration of Fortified Procaine Penicillin should be discontinued and appropriate treatment given.

Penicillin should be used with caution in individuals with histories of significant allergies and/or asthma. Care should be taken to avoid intravenous or intra-arterial administration, or injection into or near major peripheral nerves or blood vessels, since such injections may produce neurovascular damage.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

The efficacy of oral contraceptives may be impaired under concomitant administration of Fortified Procaine Penicillin, which may result in unwanted pregnancy.

There is reduced excretion of methotrexate when used with Fortified Procaine Penicillin.

Probenecid inhibits tubular secretion of Fortified Procaine Penicillin and so may be given to increase the plasma concentrations.

4.6 Pregnancy and Lactation

Pregnancy

Fortified Procaine Penicillin has been taken by a large number of pregnant women and women of childbearing age without an increase in malformations or other direct or indirect harmful effects on the foetus having been observed.

Lactation

It is not known if Fortified Procaine Penicillin may be excreted into the breast milk of nursing mothers, it is actively transported from the blood to milk in animals and trace amounts of other penicillin in human milk have been detected.

4.7 Effects on Ability to Drive and Use Machines

None stated

4.8 Undesirable Effects

Urticaria, Anaphylaxis

4.9 Overdose

Excessive blood levels of benzylpenicillin sodium can be corrected by haemodialysis.

5.0 Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Beta-lactamase sensitive penicillins.

ATC code: J01CE01.

Fortified Procaine Penicillin exerts a bactericidal action against penicillin-susceptible microorganisms during the stage of active multiplication. It acts through the inhibition of biosynthesis of cell-wall mucopeptide.

5.2 Pharmacokinetic Properties

Fortified procaine penicillin is an equimolecular compound of procaine and Fortified Procaine Penicillin, 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 Fortified Procaine Penicillin 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 Fortified Procaine Penicillin is excreted in the urine within 24 to 36 hours.

5.3 Preclinical Safety Data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

6. Pharmaceutical Particulars

6.1 List of Excipients

None.

6.2 Incompatibilities

None

6.3 Shelf Life

<36 Months>

<Use immediately after opening the ampoule>

6.4 Special Precautions for Storage

Store below 25°C. Keep all medicines out of reach of children.

6.5 Nature and Contents of Container

10vial packed in a carton along with patient information leaflet.

Primary container : Clear glass vial.

Secondary Container: Sticker, Carton, Pack Insert

6.6 Special Precautions for Disposal and Other Handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Registrant/Sole Agent

EMBASSY PHARMACEUTICAL & CHEMICAL LTD.

41, Ademola Street, South West Ikoyi,

Lagos, Nigeria, Tel.: 01-2900791

8. Manufacturer

LABORATE PHARMACEUTICALS INDIA LIMITED

51, Industrial Area, Gondpur, Paonta Sahib, Himachal Pradesh (INDIA)

HO:E-11, Indl. Area, Panipat – 132 103

E-mail: laborate@laborate.com

9. Date of Revision of Text

To be given after approval of product

10. Dosimetry (If applicable)

Not applicable

11. Instructions for Preparation of Radiopharmaceuticals (If applicable)

Not applicable