Summary of Product Characteristics

FLAPODIN

1. Name of the Medicinal Product

FLAPODIN Fortified Procaine Penicillin Injection 4 Mega (Fortified Procaine Penicillin for Injection 4 Mega)

2. Quantitative and Qualitative Composition:

Each Vial contains:

Procaine Penicillin BP 3.0g (3,000,000 IU).

Benzyl Penicillin Sodium BP 0.6 g (1,000,000 IU)

Buffering Agents: Anhydrous Sodium CMC USP

3. Pharmaceutical Forms:

Powder for Injection.

4. Clinical particulars:

4.1Therapeutic indication:

Fortified Procaine Penicillin Injection 4 mega is indicated for most wound infections, pyogenic infections of the skin, soft infections and infections of the nose, throat, nasal sinuses, respiratory tract and middle ear. It is also indicated for the following infections caused by penicillin-sensitive

Microorganisms: Generalised 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 Bstreptococcal infections. Complications secondary to gonorrhoea and syphilis (e.g. gonococcal arthritis or endocarditis, congenital syphilis and neurosyphilis).

Diphtheria, brain abscesses and pasteurellosis. Consideration should be given to official local guidance (e. g. national recommendations) on the appropriate use of antibacterial agents. Susceptibility of the causative organism to the treatment should be tested (if possible), although therapy may be initiated before the results are available

4.2 Posology and Method of Administration:

Route of administration:

Intramuscular,

Dosage:

Intramuscular is the only route of administration. For general purposes a common adults dosage is 1 Mega of Fortified Procaine Penicillin intramuscularly once or twice a day. The dose should be reduced in neonates and when renal disease is present.

4.3 Contraindication:

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 Special Precaution for Use:

Benzylpenicillin sodium:

Blood and Lymphatic System Disorders

Rare (0.01% - 0.1%)

Haemolytic anaemia and granulocytopenia (neutropenia), agranulocytosis, leucopenia and thrombocytopenia, have been reported in patients receiving prolonged high doses of benzylpenicillin sodium (eg. Subacute bacterial endocarditis).

Immune System Disorders

Very Common (>10%)

Patients undergoing treatment for syphilis or neurosyphilis with benzylpenicillin may develop a Jarisch-Herxheimer reaction.

Common (1-10%)

Hypersensitivity to penicillin in the form of rashes (all types), fever, and serum sickness may occur (1-10% treated patients).These may be treated with antihistamine drugs.

Rare (0.01%-0.1%)

More rarely, anaphylactic reactions have been reported (<0.05% treated patients).Nervous System Disorders

Rare (0.01%-.01%)

Central nervous system toxicity, including convulsions, has been reported with massive doses over 60 g per day and in patients with severe renal impairment.

Renal and Urinary Disorders

Rare (0.01%-0.1%) Interstitial nephritis has been reported after intravenous benzylpenicillin sod ium at doses of more than 12 g per day.

Procaine penicillin

Diarrhea that is watery or bloody;
Peeling skin, severe pain, or changes in skin color where the medicine was injected;
Dizziness, joint or muscle pain;
Fast or pounding heartbeats;
Numbness, tingling, pain, swelling, or redness in your arms or
Legs; confusion, agitation, depression, unusual thoughts or
Behavior; chest pain, problems with vision or speech;
Feeling like you might pass out;
Fever, chills, dizziness, muscle pain, rapid breathing or heart rate;
Uncontrolled muscle movements, problems with balance or
Walking; pale skin, easy bruising or bleeding, unusual weakness;
Sore throat, flu symptoms;
Urinating less than usual or not at all;
Rash or itching with swollen glands, joint pain, or general ill feeling;
Or slow heart rate, weak pulse, fainting, slow breathing.

4.5 Interaction with Other Medicaments:

If you use other drugs or over the counter products at the same time, the effects of Fortified Procaine Penicillin Injection may change. This may increase your risk for side-effects or cause your drug not to work properly. Tell your doctor about all the drugs, vitamins, and herbal supplements you are using, so that you doctor can help you prevent or manage drug interactions. Fortified Procaine Penicillin Injection may interact with the following drugs and products:

- Alcohol
- Alcuronium
- Amiodarone
- Amitriptyline
- Amphotericin B
- Artemisinin

4.6 Pregnancy and Lactation:

Before using Fortified Procaine Penicillin Injection, inform your doctor about your current list of medications, over the counter products (e.g. vitamins, herbal supplements, etc.), allergies, pre-existing

diseases, and current health conditions (e.g. pregnancy, upcoming surgery, etc.).Some health conditions may make you more susceptible to the side-effects of the drug. Take as directed by your doctor or follow the direction printed on the product insert. Dosage is based on your condition. Tell your doctor if your condition persists or worsens. Important counseling points are listed below.

 Birth control and hormonal contraception may not work as well. Use another form of contraception such as condom

 Breastfeeding

 Diarrhea

 Do not self-inject this medicine if you do not fully understand how to give the injection

 Given as intramuscular shot

 May experience diarrhea from this medication

4.7 Effects on ability to drive and use machines:

If you experience drowsiness, dizziness, hypotension or a headache as side-effects when using Fortified Procaine Penicillin Injection medicine then it may not be safe to drive a vehicle or operate heavy machinery.

4.8 Undesirable Effects:

The following is a list of possible side-effects that may occur from all constituting ingredients of Fortified Procaine Penicillin Injection. This is not a comprehensive list. These side-effects are possible, but do not always occur. Some of the side-effects may be rare but serious. Consult your doctor if you observe any of the following side-effects, especially if they do not go away.

 Bleeding at site of injection

 Mild diarrhea

 Pain

 Swelling

 Similar to penicillin g sodium

4.9 Overdose:

Do not use more than prescribed dose. Taking more medication will not improve your symptoms; rather they may cause poisoning or serious side-effects. If you suspect that you or anyone else who may have overdosed of Fortified Procaine Penicillin Injection, please go to the emergency department of the closest hospital or nursing home.

5 Pharmacological Properties:

5.1. Pharmacodynamic properties

ATC classification: J01CE09

Mode of action

It is a form of penicillin which is a combination of benzylpenicillin and the local anaesthetic agent procaine. Following deep intramuscular injection, it is slowly absorbed into the circulation and hydrolysed to benzylpenicillin — thus it is used where prolonged low concentrations of benzylpenicillin are required.

5.2 Pharmacokinetics Properties:

Absorption:

After intramuscular injection, 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.

Volume of Distribution:

The drug is distributed throughout the body tissues in widely varying amounts and spinal fluid to a lesser degree. Highest levels are found in the kidneys with lesser amounts in the liver, skin, and intestines. It displays low solubility thus results in blood serum levels much lower but more prolonged than other parenteral penicillins.

Protein Binding:

Approximately 60% of penicillin G is bound to serum protein.

Metabolism:

Procaine is rapidly hydrolyzed by plasma esterases to nontoxic metabolites.

Route of elimination:

The drug is rapidly and predominantly cleared via renal elimination, with 90% being through tubular secretion. Approximately 60 -90 % of a dose of parenteral penicillin G is excreted in the urine within 24 to 36 hours.

Half life

Intramuscular injection of benzylpenicillin has a plasma half-life of 30 minutes

5.3 Preclinical Safety Data:

There is no preclinical safety data of relevance to the prescriber that are additional to those included in other sections.

6 Pharmaceutical Particulars:

6.1 List of Excipients

Sodium Citrate, Sodium Carboxy Methyl cellulose & Citric acid anhydrous.

6.2 Incompatibilities:

Not applicable

6.3 Shelf Life:

48 months.

6.4 Special Precaution for Storage:

Store below 30°C. Protect from light.

6.5 Nature and contents of container

FLAPODIN Fortified Procaine Penicillin Injection 4 Mega is packed in 20 mL USP type III vial such 10 vials are packed in a carton along with pack insert.

6.6 Special precautions for disposal

Not applicable.

7 Marketing Authorization Holder

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