PATIENT INFORMATION LEAFLET FOR HUMAN MEDICINES

SCHEDULING STATUS:

S4

Benzathine Penicillin 2,4 Cospharm

Powder for solution for intramuscular injection

Benzathine Benzylpenicillin

Sugar free

Read all of this leaflet carefully before you are given Benzathine Penicillin 2,4 Cospharm

- *Keep this leaflet. You may need to read it again.*
- *If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.*

What is in this leaflet:

1. What Benzathine Penicillin 2,4 Cospharm is and what it is used for

2. What you need to know before you are given Benzathine Penicillin 2,4 Cospharm

3. How Benzathine Penicillin 2,4 Cospharm should be administered to you

4. Possible side effects

5. How to store Benzathine Penicillin 2,4 Cospharm

6. Contents of the pack and other information

1. What Benzathine Penicillin 2,4 Cospharm is and what it is used for

It is an antibiotic. It contains the active substance called Benzathine Benzylpenicillin. It belongs to a family of medicines called 'penicillins'.

It works by killing certain bacteria which cause infections.

It is used for treatment of:

- Syphilis

It is used for prevention of:

- Rheumatic fever

2. What you need to know before you are given Benzathine Penicillin 2,4 Cospharm

Benzathine Penicillin 2,4 Cospharm should not be administered:

- If you are hypersensitive (allergic) to the active substance benzathine benzylpenicillin or other penicillins.
- To babies in the neonatal period born of mothers hypersensitive to penicillins.

Warnings and precautions

Tell your doctor or health care provider before being given Benzathine Penicillin 2,4 Cospharm if:

- you have ever had an allergic reaction to other antibiotics like penicillin or other beta-lactam antibiotics;
- you have kidney problems (your doctor may need to adjust the dose of this medicine);
- you have severe liver problems.

Benzathine Penicillin 2,4 Cospharm should not be used in tissues with poor blood flow.
If allergic symptoms occur (skin rash, itching or shortness of breath), tell the doctor immediately.
Before treatment, a hypersensitivity test should be performed, if possible. If an allergic reaction occurs, your doctor will stop treatment and if necessary, start appropriate therapy.
A possible cross-allergy should be considered in patients with hypersensitivity to cephalosporins.
Please tell your doctor or healthcare provider if you have had a previous allergic reaction to certain antibiotics (cephalosporins).
If you have already been diagnosed with an allergy and/or allergic asthma or hay fever, you should tell your doctor.
Severe immediate allergic reactions are possible even when the medicine is administered for the first time. Based on general principles, in particular in some cases, you will remain under observation for

at least half an hour after the medicine has been administered, in case an acute allergic reaction should occur.
If an allergy occurs, the doctor will take appropriate measures. Treatment with Benzathine Penicillin 2,4 Cospharm must be stopped immediately.

When treating syphilis, a bodily reaction to the bacterial toxins may occur, which lasts up to several days (Jarisch-Herxheimer reaction, see section 4).
Typical symptoms are sudden fever (sometimes with chills), pale skin; followed by skin redness, headache, painful muscles and joints or tiredness.
To suppress or alleviate a Jarisch-Herxheimer reaction, your doctor will start appropriate therapy.
Dose adjustments are necessary in patients with impaired kidney function and in patients with impaired liver function.

Other medicines and Benzathine Penicillin 2,4 Cospharm
Always tell your health care provider if you are taking any other medicine.
(This includes all complementary or traditional medicines.)
Caution should be exercised when administering Benzathine Penicillin 2,4 Cospharm at the same time as the following medicines:

- bacteriostatic antibiotics
- probenecid, a medicine used to treat gout
- methotrexate, a medicine used in chemotherapy. The combination with methotrexate is not recommended
- anti-coagulants: medicines used to prevent clotting of the blood.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before being given this medicine.

Pregnancy:

Benzathine Penicillin 2,4 Cospharm can be used during pregnancy after appropriate diagnosis and careful consideration of the benefits and risks by the prescribing doctor.

Breastfeeding:

Small amounts of benzylpenicillin, the active substance, pass into breast milk.

Although no side effects have been reported to date in young infants fed on breast milk, the possibility of sensitisation or interference with the intestinal flora must nevertheless be considered. In the case of occurrence of diarrhoea, candidiasis (fungal infection) or rash in the child, ask immediately your doctor who will give you an advice, because these disorders in the child could be due to Benzathine penicillin. In young infants also being fed on baby food, mothers receiving should express and discard their breast milk.

They can start breast-feeding again 24 hours after completion of treatment.

Driving and using machines

This medicine can impair responsiveness and the ability to drive. Due to the occurrence of possible serious side effects (e.g. anaphylactic shock with collapse and anaphylactoid reactions), it can have a major influence on the ability to drive and use machines.

It is not always possible to predict to what extent Benzathine Penicillin 2,4 Cospharm may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which Benzathine Penicillin 2,4 Cospharm affects them.

Benzathine Penicillin 2,4 Cospharm contains anhydrous sodium

Citrate, which is used to adjust the pH.

3. How Benzathine Penicillin 2,4 Cospharm should be administered to you.

The adult dosage is as follows:

- for syphilis: 2,4 Mega Units
- for the recurrence of rheumatic fever: 1,2 Mega Units every 3 to 4 weeks.

Benzathine Penicillin 2,4 Cospharm will be given to you by a person who is qualified to do so.

The preparation may only be injected into muscle (intramuscular administration).

The injection must not be administered into tissue with poor blood flow. In case of repeated intramuscular application, the site of injection site must be changed. Severe local reactions may occur during intramuscular administration, especially in young children. For this reason, other treatments such as a different penicillin formulation can be used where possible.

If you have impaired kidney or liver function, the dosage and dosing interval will be determined by your doctor.

If you have the impression that the effects of Benzathine Penicillin 2,4 Cospharm is too strong or too weak, tell your doctor.

If you receive more Benzathine Penicillin 2,4 Cospharm than you should

At extremely high doses, penicillins can cause neuromuscular excitability or epileptiform seizures.

Since a health care provider will administer Benzathine Penicillin 2,4 Cospharm, he/ she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of Benzathine Penicillin 2,4 Cospharm

Since a health care provider will administer Benzathine Penicillin 2,4 Cospharm it is unlikely that the dose will be missed.

4. Possible side effects

Benzathine Penicillin 2,4 Cospharm can have side effects.

Not all side effects reported for Benzathine Penicillin 2,4 Cospharm are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Benzathine Penicillin 2,4 Cospharm, please consult your health care provider for advice.

Frequent side effects:

- Fungal infection
- Diarrhoea
- Feeling sick (nausea)
- Changes in certain test and investigation results performed by your doctor
- Inflammation of the lining of the mouth (stomatitis) and of the tongue (glossitis)
- Being sick (vomiting)

Less frequent side effects

- Allergic reactions including:
- nettle rash (urticaria)
- swelling (angioedema)
- skin reactions (erythema multiforme, exfoliative dermatitis)
- skin rashes
- fever
- painful joints (arthralgia)
- anaphylactic shock with collapse and asthma, skin bleeding (purpura) and gastrointestinal complaints (anaphylactoid reactions)
- Kidney disease (nephroplasty)
- Kidney inflammation (interstitial nephritis)
- Certain blood disorders (so called haemolytic anaemia, leukopenia, thrombocytopenia, agranulocytosis)

Frequency unknown

- Prolongation of bleeding time and defective functioning of platelets
- Sensitivity reaction with urticaria (hives), fever, pain in the joints and eosinophilia (increase in the amount of white blood cells)
- Sore mouth and black hairy tongue
- Seizures
- Heartburn
- Serum sickness
- Inflammation of the large intestine (pseudomembranous colitis)
- Liver inflammation (hepatitis)
- Impairment of bile flow (cholestasis)
- Pain at the injection site
- Injection site infiltrates
- Penicillin psychosis (Hoigne and Nicolau Syndrome)
- In patients with kidney problems or kidney failure, the risk of neurotoxicity and heart failure is increased when high doses of the medicine are given.

Reporting of side effects

If you get side effects, talk to your doctor or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za. By reporting side effects, you can help provide more information on the safety of Benzathine Penicillin 2,4 Cospharm.

5. How to store Benzathine Penicillin 2,4 Cospharm

- Store all medicines out of reach of children.
- Store at or below 30 °C until it is ready to be used to create a solution.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Benzathine Penicillin 2,4 Cospharm contains:

The active ingredient is Benzathine Benzylpenicillin, each vial contains 2,015 g Benzathine Benzylpenicillin equivalent to 2 400 000 I.U. powder for solution for intramuscular injection and Anhydrous Sodium Citrate as a buffering agent.

What Benzathine Penicillin 2,4 Cospharm looks like and contents of the pack

Benzathine Penicillin 2,4 Cospharm is a white or almost white crystalline powder in a 20 ml USP Type III glass vial.

Holder of Certificate of Registration

Cospharm Investments (Pty) Ltd.

2 Concourse Crescent

Lonehill

Sandton, 2191

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