Annotated Proposed Patient Information Leaflet (PIL)
for Medicines for Human Use
AMPICILLIN INJECTION UNIMED

SCHEDULING STATUS: S4

AMPICILLIN 250 INJECTION UNIMED

AMPICILLIN 500 INJECTION UNIMED

Ampicillin

Sugar free

Read all of this leaflet carefully before you are given AMPICILLIN INJECTION UNIMED**.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- AMPICILLIN INJECTION UNIMED has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. WHAT AMPICILLIN INJECTION UNIMED IS AND IT IS USED FOR:

AMPICILLIN INJECTION UNIMED belongs to a group of medicines called broad spectrum antibiotics. It is used to kill bacteria that cause infections in your body.

AMPICILLIN INJECTION UNIMED is used to treat infections in various organs.

AMOICILLIN INJECTION UNIMED works by killing bacteria that cause infections, such as:

- Ear, nose and throat infections
- Bronchitis, pneumonia, chest infections
- Urinary tract infections
- Sexually transmitted infections
- Skin and soft tissue infections
- Gastrointestinal infections

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE ADMINISTERED AMPICILLIN INJECTION UNIMED:

You should not be administered AMPICILLIN INJECTION UNIMED:

— if you are hypersensitive (allergic) to ampicillin, any other penicillin or cephalosporin type antibiotics or cephamycins

— AMPICILLIN INJECTION UNIMED is not recommended in babies born of hypersensitive mothers in the neonatal period.

Special care should be taken with AMPICILLIN INJECTION UNIMED:

- if you are allergic to penicillin anaphylactic shock may occur (see **'You should not be administered AMPICILLIN INJECTION UNIMED'** above). AMPICILLIN INJECTION UNIMED should be stopped and emergency help given if you have any of these signs of allergic reaction: difficulty breathing, swelling of your face, lips, tongue or throat, chest pains.
- if you develop skin rashes while receiving AMPICILLIN INJECTION UNIMED, tell

your doctor. Treatment with AMPICILLIN INJECTION UNIMED should be stopped

- if you have bacterial infections caused by spirochete such as syphilis, as the Jarisch- Herxheimer reaction may occur shortly after starting treatment. This reaction, manifesting as fever, chills, headache and reactions at the site of the lesion, can be dangerous in cardiovascular syphilis (infection of the heart and related blood vessels by the syphilis bacteria) or where there is a serious risk of increased local damage such as with optic atrophy (eye problem)
- if you have poor kidney functioning or any heart disease. In case of long term treatment or high dose administration, kidney function and blood test should be performed. Your doctor may need to reduce your dosage.
- Tell your doctor if you have infectious mononucleosis (glandular fever), lymphatic leukaemia (cancer of the blood), or HIV infection, or if you are taking a medicine called allopurinol. This is increased possibility of skin rashes occurring in patients taking AMPICILLIN INJECTION UNIMED with these conditions.
- Tell your doctor if you have a bleeding or blood clotting disorder.
- A serious form of diarrhoea (pseudomembranous colitis) may develop if you use AMPICILLIN INJECTION UNIMED for a long period of time. Contact your doctor right away if stomach pain or cramps, severe diarrhoea, or bloody stools occur.
- In long term therapy, and particularly with high dosage regimens, periodic evaluation of the kidney, liver and blood systems is recommended.
- Following long-term treatment, numbness; tingling; pins and needles has rarely been reported.
- AMPICILLIN INJECTION UNIMED can cause interference in some tests for glucose in urine. Penicillins which are excreted in urine can cause a false-positive result. Your doctor will request a test which is not affected by penicillins.
- AMPICILLIN INJECTION UNIMED may interfere with certain laboratory tests. Be sure your doctor and laboratory personnel know you are using AMPICILLIN INJECTION

UNIMED.

- If you are receiving high doses, make sure that you take enough fluids.

Children:

- The lowest effective dose of AMPICILLIN INJECTION UNIMED should be administered to neonates and young infants as their kidney function is still not developed completely and this may cause a delay in excretion of the active substance ampicillin in AMPICILLIN INJECTION UNIMED.

Taking other medicines with AMPICILLIN INJECTION UNIMED:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Tell your doctor, if you are taking:

- oral contraceptives (levonorgestrel, norethindrone, ethinyl estradiol)
- medicines used to kill infection caused by bacteria (for example chloramphenicol, tetracycline, erythromycin, sulphonamide)
- probenecid and allopurinol, used for gout (a disease which results in arthritis or pain in bones).
- After treatment with AMPICILLIN INJECTION UNIMED, a false positive reaction for glucose in the urine may occur with copper sulfate tests but not with enzyme based tests such as Clinistrix. Please inform your doctor that you are receiving AMPICILLIN INJECTION UNIMED.
- Lignocaine – Lignocaine should only be used together with AMPICILLIN INJECTION UNIMED, when AMPICILLIN INJECTION UNIMED is injected into a muscle, and must not be given into a vein.
- Preparations for thinning blood (e.g. warfarin, heparin) – Your doctor may want to monitor your blood clotting time more frequently if you are receiving anticoagulant

treatment in combination with AMPICILLIN INJECTION UNIMED.

- NSAIDs (non-steroidal anti-inflammatory drugs) or salicylates (e.g. aspirin) – The risk of bleeding is increased when these medicines are used together with AMPICILLIN INJECTION UNIMED.
- Aminoglycoside antibiotics (e.g. gentamycin) and cephalosporin antibiotics AMPICILLIN INJECTION UNIMED should not be mixed in the same syringe or administration set with these antibiotics.
- Methotrexate, used to treat cancer – AMPICILLIN INJECTION UNIMED may decrease the removal of methotrexate from the body, increasing the risk of its side-effects. Your doctor may want to monitor the amount of methotrexate in your blood if you are receiving methotrexate treatment in combination with AMPICILLIN INJECTION UNIMED.
- ACE inhibitors, potassium-sparing diuretics, potassium containing medicines or potassium supplements – Use of these medicines together with AMPICILLIN INJECTION UNIMED may cause too much potassium in the blood, especially in patients with kidney problems.

Receiving AMPICILLIN INJECTION UNIMED with food or drink:

AMPICILLIN INJECTION UNIMED may be administered before or after meals.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before you receive AMPICILLIN INJECTION UNIMED.

Safety in pregnancy and breast-feeding has not been established.

Ampicillin class of antibiotics are excreted in milk. Use of AMPICILLIN INJECTION UNIMED in breast-feeding mothers may cause allergy (skin rash), diarrhoea and fungal infection such

as candidiasis in new born.

Driving and using machinery:

AMPICILLIN INJECTION UNIMED may cause dizziness.

Do not drive or operate any tools or machines until you know how AMPICILLIN INJECTION UNIMED affects you because your concentration may be affected.

AMPICILLIN INJECTION UNIMED contains sodium

Sodium content must be taken into account in patients on a sodium-restricted diet if the administration of high doses is necessary

AMPICILLIN 250 INJECTION UNIMED: This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially ‘sodium-free’.

AMPICILLIN 500 INJECTION UNIMED: This medicinal product contains 30,96 mg sodium per 500 mg vial, equivalent to 1.55 % of WHO recommended maximum daily intake of 2 g sodium for an adult.

3. HOW AMPICILLIN INJECTION UNIMED IS GIVEN:

Do not share medicines prescribed for you with any other person.

The injection is used to treat serious infections that cannot be treated by oral ampicillin. You should check with your doctor or pharmacist if you are unsure.

Children: The usual dose is up to 400 mg per kilogram body mass to be used after every 4 hours in a day.

Adults: The usual dose is up to 12 g to be used after every 4 hours in a day.

Doses for children should not exceed doses recommended for adults.

Your doctor will recommend the dose according to the type and seriousness of the infection, your kidney function and age and may administer the injection either directly into the veins or

intramuscularly or in the form of intravenous drip.

You will not be expected to give yourself AMPICILLIN INJECTION UNIMED. It will be given to you by a person who is qualified to do so.

If you have the impression that the effect of AMPICILLIN INJECTION UNIMED is too strong or too weak, tell your doctor or pharmacist.

If you receive more AMPICILLIN INJECTION UNIMED than you should:

Since a healthcare professional will administer AMPICILLIN INJECTION UNIMED, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of AMPICILLIN INJECTION UNIMED:

Do not receive a double dose to make up for forgotten individual doses.

Effects when treatment with AMPICILLIN INJECTION UNIMED is stopped:

Your doctor will tell you how long your treatment with AMPICILLIN INJECTION UNIMED will last.

4. POSSIBLE SIDE EFFECTS:

AMPICILLIN INJECTION UNIMED can have side effects.

Not all side effects reported for AMPICILLIN INJECTION UNIMED are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while receiving AMPICILLIN INJECTION UNIMED, please consult your doctor, pharmacist or other healthcare professional for advice.

~~**Very serious side effects**~~

If any of the following happens, stop receiving AMPICILLIN INJECTION UNIMED and tell your doctor immediately or go to the casualty department at your nearest hospital:

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing (sudden life-threatening allergic reaction),
- allergic reactions include severe flaking or peeling of the skin (exfoliative dermatitis), skin rashes with coloured spots on the skin (maculopapular rash), severe condition of the skin that may affect the mouth and other parts of the body (erythema multiforme), redness of skin with itching (urticaria), and other skin rashes,
- entire body rash including the rash of sole, palms and oral cavity which usually develops after the first week of therapy.
- chest pain in context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to AMPICILLIN INJECTION UNIMED. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- a condition in which there is a decreased number of red blood cells (symptoms include tiredness, headaches, being short of breath when exercising, dizziness and looking pale),
- a blood disorder that causes blood clots around the body and leads to low platelet count. These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent

- diarrhoea, feeling sick (nausea), being sick (vomiting),

Less frequent

- fever with constriction of voice box (laryngeal stridor),
- bacterial infection causing inflammation of colon (pseudomembranous colitis),
- convulsions and paraesthesia (numbness, tingling, pins and needles)
- lack of white blood cells (symptoms include frequent infections such as fever, severe chills, sore throat or mouth ulcers),
- low blood platelet count (thrombocytopenia) due to which bleeding occurs more easily than normal.

Frequency unknown

- sore mouth or tongue,
- black hairy tongue
- mucocutaneous candidiasis and antibiotic-associated colitis (haemorrhagic colitis)
- crystals found in the urine (leading to acute kidney injury)
- increased muscle activity, dizziness
- heartburn
- inflammation of the liver (hepatitis) and yellow pigmentation of skin and eyes (cholestatic jaundice)
- rash with blisters arranged in a circle with central crusting or like a string of pearls (Linear IgA disease)

Laboratory abnormalities:

— Abnormal level of liver enzyme,

— Abnormal blood cell counts.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of AMPICILLIN INJECTION UNIMED.

5. HOW TO STORE AMPICILLIN INJECTION UNIMED

- Store at or below 25 0C
- Protect from moisture
- Use the prepared solution immediately
- Keep out of reach of children

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What AMPICILLIN INJECTION UNIMED contains

The active substance is:

Ampicillin sodium BP equivalent to ampicillin anhydrous 250 mg; or Ampicillin sodium BP equivalent to ampicillin anhydrous 500 mg.

AMPICILLIN INJECTION UNIMED contains no other ingredients.

What AMPICILLIN INJECTION UNIMED looks like and contents of the pack

AMPICILLIN 250 INJECTION UNIMED:

White to off-white crystalline, odourless, hygroscopic powder in a 5 ml clear glass USP type III vial sealed with a grey butyl rubber plug and tear off golden yellow aluminium seal.

AMPICILLIN 500 INJECTION UNIMED:

White to off-white crystalline, odourless, hygroscopic powder in a 5 ml clear glass USP type III vial sealed with a grey butyl rubber plug tear off silver aluminium seal.

After reconstitution, a clear, colourless to pale yellow solution, free from visible particles is formed.

AMPICILLIN INJECTION UNIMED are packed in

AMPICILLIN 250 INJECTION UNIMED: Carton containing 5, 50 or 100 clear glass USP type III vials.

AMPICILLIN 500 INJECTION UNIMED: Carton containing 5, 50 or 100 clear glass USP type III vials.

Holder of certificate of registration

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