SCHEDULING STATUS: S4

PROPRIETARY NAME (AND DOSAGE FORM):
AMOXICILLIN 125 mg/5 ml SUSPENSION UNIMED
AMOXICILLIN 250 mg/5 ml SUSPENSION UNIMED

COMPOSITION:

Amoxicillin 125 mg/5 ml Suspension Unimed

Each 5 ml contains:

Amoxicillin trihydrate equivalent to amoxicillin anhydrous	125 mg
Contains sugar: Sorbitol	0,73 g
Contains sweetener: Saccharin sodium	9 mg

Amoxicillin 250 mg/5 ml Suspension Unimed

Each 5 ml contains:

Amoxicillin trihydrate equivalent to amoxicillin anhydrous	250 mg
Contains sugar: Sorbitol	0,58 g
Contains sweetener: Saccharin sodium	9 mg

Excipients: Colloidal anhydrous silica, sodium citrate, xanthan gum, colouring & flavouring agents.

PHARMACOLOGICAL CLASSIFICATION:

A 20.1.2 Penicillins

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

Amoxicillin trihydrate is a semisynthetic penicillinase susceptible penicillin, an analogue of ampicillin, with a broad spectrum of *in-vitro* bactericidal activity against many Gram-positive and Gram-negative micro-organisms.

In vitro sensitivity does not necessarily imply *in-vivo* efficacy.

Resistant strains: *Enterobacter, Pseudomonas, Klebsiella, Serratia, Acinetobacter* and indole-positive *Proteus*.

Pharmacokinetic properties:

Amoxicillin is resistant to inactivation by gastric acid and may be given without regard to meals. It is well absorbed after oral administration. Amoxicillin is not highly protein-bound. Orally administered doses of 250 mg and 500 mg amoxicillin result in average peak blood levels one to two hours after administration in the range of 3,5 µg/ml to 5,0 µg/ml and 5,5 µg/ml to 7,5 µg/ml respectively.

Detectable serum levels are observed up to 8 hours after an orally administered dose of amoxicillin. It diffuses readily into most body tissues and fluids, with the exception of brain and spinal fluid, except when meninges are inflamed. The half-life of amoxicillin is 1 to 1,5 hours. Approximately 60 percent of an orally administered dose of amoxicillin is excreted unchanged in the urine within six to eight hours by glomerular filtration and tubular secretion. Amoxicillin is removed by haemodialysis. High concentrations have been reported in bile; some may be excreted in faeces.

INDICATIONS:

Amoxicillin Suspension Unimed is indicated in the treatment of infections due to susceptible non-penicillinase producing strains of the following:

- Infections of the ear, nose and throat due to streptococci, pneumococci, nonpenicillinase-producing staphylococci and *H. influenzae*.
- Infections of the genitourinary tract due to *E. coli, Proteus mirabilis* and *Streptococcus faecalis*.
- Infections of the skin and soft-tissues due to streptococci, susceptible staphylococci and *E. coli*.
- Infections of the lower respiratory tract due to streptococci, pneumococci, non-penicillinase producing staphylococci and *H. influenzae*.
- Gonorrhea, acute uncomplicated ano-genital and urethral infections due to *N. gonorrhoea* (males and females).

CONTRAINDICATIONS:

A history of allergic reactions to amoxicillin, any of the penicillins or cephalosporins.
Hypersensitivity to any of the other excipients of **Amoxicillin Suspension Unimed**.
Infectious mononucleosis.
It is contra-indicated in babies born to mothers hypersensitive to amoxicillin or any other penicillins, and in the neonatal period.
Patients with lymphatic leukemia.

Patients with hyperuricaemia being treated with allopurinol may also be at an increased risk of developing skin rashes.

WARNINGS and SPECIAL PRECAUTIONS:

When administered to a patient with penicillin sensitivity, anaphylactic shock may occur. Life support, epinephrine (adrenaline), corticosteroids and antihistamines should be used to treat anaphylaxis.

Use with caution in patients with known history of allergy.

Before initiating therapy with any penicillin, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other allergens. If any allergic reaction occurs, appropriate therapy should be instituted and discontinuance of **Amoxicillin Suspension Unimed** therapy considered.

Sensitivity reactions are more likely to occur in individuals who have previously demonstrated hypersensitivity to penicillins and in those with a history of allergy, asthma, hay fever or urticaria. Patients with lymphatic leukaemia or possibly HIV infection may also be at increased risk of developing skin rashes. Treatment with **Amoxicillin Suspension Unimed** should be stopped if a rash occurs.

Periodic assessment of renal, hepatic and hematopoetic function should be made during prolonged therapy with **Amoxicillin Suspension Unimed**.

Pseudomembranous colitis has been reported.

The possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur (usually involving *Enterobacter, Pseudomonas* or *Candida*), **Amoxicillin Suspension Unimed** should be discontinued and/or appropriate therapy instituted.

Care should be taken when treating patients with 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 or where there is a serious risk of increased local damage such as with optic atrophy.

Care should be taken when high doses are given to patients with renal impairment (because of the risk of neurotoxicity) or congestive heart failure.

Caution must be exercised when treating patients with dehydration or oliguria because of the possibility of crystalluria.

Effects on ability to drive and use machines:

Amoxicillin Suspension Unimed may cause dizziness or confusion. Caution is advised for patients to not drive or use machines, until their individual susceptibility to the effects of **Amoxicillin Suspension Unimed** is known.

INTERACTIONS:

Amoxicillin Suspension Unimed may decrease the efficacy of oral contraceptives and may cause increased breakthrough bleeding. Probenecid can delay the excretion of **Amoxicillin Suspension Unimed** when given concurrently.

The possibility of a prolonged bleeding time (increase in INR) after oral treatment with **Amoxicillin Suspension Unimed** in patients receiving anticoagulants such as warfarin.

Amoxicillin Suspension Unimed may interfere with some diagnostics tests such as for urinary glucose using copper sulphate, direct antiglobulin (Coomb') tests for urinary or serum proteins. **Amoxicillin Suspension Unimed** may interfere with tests that use bacteria, for example the Guthrie test for phenylketonuria using *Bacillus subtilis* organisms.

PREGNANCY AND LACTATION:

Animal reproduction studies have failed to demonstrate a risk to the foetus and there are no adequate and well controlled studies in pregnant women.

DOSAGE AND DIRECTION FOR USE:

Paediatric dose:

Infants up to 6 kg body weight:	25-50 mg every eight hours.
Infants 6 to 8 kg body weight:	50-100 mg every eight hours.
Infants and children 8-20 kg body weight:	6,7-13,3 mg per kg body weight every eight hours.
Children 20 kg of body weight and over:	250-500 mg every eight hours.

Adults who are not able to take capsules may be given **Amoxicillin Suspension Unimed**.

Usual Adult dose: 250-500 mg every eight hours.

Maximum dose up to 4,5 g a day.

Directions for mixing:

Add 64 ml and 85 ml water for 75 ml and 100 ml pack respectively in two portions to dry mixture in the bottle. Shake well after each addition.

SIDE EFFECTS:

Blood and the lymphatic system disorders

Less frequent: Anaemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia and granulocytopenia.

Immune system disorders

Less frequent: Hypersensitivity reactions (including erythematous maculopapular rashes, urticaria, fever and joint pains). Anaphylactic shock.

Nervous system disorders

Less frequent: Reversible hyperactivity, agitation, anxiety, insomnia, confusion, behavioural changes and/or dizziness.

Vascular disorders

Less frequent: Vasculitis.

Gastro-intestinal disorders

Frequent: Nausea, heartburn, vomiting and diarrhoea.

Less frequent: Pseudomembranous colitis. A sore mouth or tongue and a black hairy tongue.

Hepato-biliary disorders

Less frequent: Hepatitis and cholestatic jaundice.

Skin and subcutaneous tissue disorders

Frequent: Skin rashes.

Less frequent: Allergic reactions which may include exfoliative dermatitis.

Renal and urinary disorders

Less frequent: Nephropathy and interstitial nephritis.

Investigations

Less frequent: A moderate rise in liver enzymes (ALT/AST) has been noted.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See Side-effects. Treatment is symptomatic and supportive.

In the event of overdosage, **Amoxicillin Suspension Unimed** can be removed by haemodialysis.

IDENTIFICATION:

Amoxicillin 125 mg/5 ml Suspension Unimed

White to off-white powder forming an orange suspension on reconstitution with water.

The resulting suspension has a characteristic flavour.

Amoxicillin 250 mg/5 ml Suspension Unimed

White to off-white powder forming an orange suspension on reconstitution with water.

The resulting suspension has a characteristic flavour.

PRESENTATION:

Amoxicillin 125 mg/5 ml Suspension Unimed

White, translucent HDPE bottle for 100 ml pack

White, translucent HDPE bottle for 75 ml pack

Amoxicillin 250 mg/5 ml Suspension Unimed

White, translucent HDPE bottle for 100 ml pack

STORAGE INSTRUCTIONS:

Store at or below 25 °C, protect from moisture.

After reconstitution the product must be stored at 2 – 8 °C in a refrigerator.

The prepared suspension should be consumed within 14 days of preparation.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS:

Amoxicillin 125 mg/5 ml Suspension Unimed: 35/20.1.2/0212

Amoxicillin 250 mg/5 ml Suspension Unimed: 35/20.1.2/0213

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

UNIMED HEALTHCARE (PTY) LTD

Corner Birch Road & Bluegum Avenue,

Anchorville,

Lenasia, 1827

South Africa

DATE OF PUBLICATION OF THE PACKAGE INSERT:

28 May 2020