SCHEDULING STATUS: **S4**

CO-AMOXICLAV S UNIMED
Powder for oral suspension
Contains sweetener (Aspartame 5 mg/5 ml)
Sugar free

CO-AMOXICLAV SF UNIMED
Powder for oral suspension
Contains sweetener (Aspartame 10 mg/5 ml)
Sugar free

(Amoxicillin and Clavulanic Acid)

Read all of this leaflet carefully before you start giving CO-AMOXICLAV UNIMED

- 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.
- CO-AMOXICLAV UNIMED has been prescribed for your child, and you should not share the medicine with other people. It may harm them, even if their symptoms are the same as your child's.

What is in this leaflet

1. What CO-AMOXICLAV UNIMED is and what it is used for

CO-AMOXICLAV UNIMED is an antibiotic and works by killing bacteria that cause infections. It contains two different medicines called amoxicillin and clavulanic acid. Amoxicillin belongs to a group of medicines called "penicillins" that can sometimes be stopped from working (made inactive). The other active component (clavulanic acid) stops this from happening.

CO-AMOXICLAV UNIMED is used in children and babies to treat the following infections:

- middle ear, sinus and throat infections
- respiratory tract infections
- urinary tract infections
- skin and soft tissue infections

2. What you need to know before you give CO-AMOXICLAV UNIMED

Do not give CO-AMOXICLAV UNIMED:

- if your child is hypersensitive (allergic) to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of CO-AMOXICLAV UNIMED. See '*Contents of the pack and other information'* in section 6.
- if your child has ever had a severe allergic reaction to any other antibiotic. This can include a skin rash or swelling of the face or throat.
- if your child has ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.
- if your child is below 2 months.

Warnings and precautions

Talk to your doctor or pharmacist before giving CO-AMOXICLAV UNIMED:

- if your child has a history of hypersensitivity (allergies) towards penicillins, other antibiotics or other allergens
- if your child has lymphatic leukaemia since this condition can bring on skin rashes when used together with the antibiotic
- if your child experiences a skin reaction after beginning treatment with the antibiotic which includes eruptions filled with pus on the top layer of the skin
- if your child has a sore throat or glandular fever
- if your child has diarrhoea after beginning or during treatment with the antibiotic
- if your child has or is being treated for liver or kidney problems
- if your child is not passing urine regularly or is passing a reduced amount of urine than normal

If you are not sure if any of the above apply to your child, talk to your doctor or pharmacist before giving CO-AMOXICLAV UNIMED.

Blood and urine tests

If your child is having blood tests (such as red blood cell status tests or liver function tests) or urine tests (for glucose), let the doctor or nurse know that your child is taking CO-AMOXICLAV UNIMED. This is because CO-AMOXICLAV UNIMED can affect the results of these types of tests.

Children and adolescents

The safe use of CO-AMOXICLAV UNIMED in children below 2 months has not been established (see 'Do not take CO-AMOXICLAV UNIMED).

Other medicines and CO-AMOXICLAV UNIMED

Always tell your health care provider if your child is taking any other medicine. This includes all complementary or traditional medicines.

- Allopurinol (used for gout) with CO-AMOXICLAV UNIMED, it may be more likely that you will have an allergic skin reaction.
- Probenecid (used for gout), your doctor may decide to adjust your dose of CO-AMOXICLAV UNIMED.
- Oral contraceptives (the "pill") with CO-AMOXICLAV UNIMED can interfere with the contraceptive's ability to work effectively.
- Medicines to help stop blood clots (such as warfarin) are taken with CO-AMOXICLAV UNIMED, then extra blood tests and adjusting your dose may be needed.
- Methotrexate (a medicine used to treat cancer or rheumatic diseases), CO-AMOXICLAV UNIMED can affect how this medicine works.
- Mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs), CO-AMOXICLAV UNIMED can affect how this medicine works.
- Concurrent use of CO-AMOXICLAV UNIMED and alcohol can cause an adverse reaction to the alcohol.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, 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 taking this medicine.

Using CO-AMOXICLAV UNIMED may interfere with the effectiveness of oral contraceptives, hence an alternative or additional method of contraception (such as condoms) should be used while taking this medicine.

The safety of CO-AMOXICLAV UNIMED in pregnancy has not been established. Both of the medicines found in CO-AMOXICLAV UNIMED are excreted into breast milk.

The use of CO-AMOXICLAV UNIMED by breastfeeding mothers may lead to the baby becoming sensitive, developing diarrhoea and fungal infections, hence you should consult with your doctor before commencing or stopping treatment.

Driving and using machines
CO-AMOXICLAV UNIMED may cause dizziness and convulsions which may affect the ability to drive or use machines.
Do not drive or operate machinery unless you are feeling well.

CO-AMOXICLAV UNIMED contains aspartame:
Aspartame (E951) is a source of phenylalanine. It may be harmful if your child has phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to give CO-AMOXICLAV UNIMED
Do not share medicines prescribed for your child with any other person.
Always give CO-AMOXICLAV UNIMED exactly as your doctor or pharmacist has told you.
Check with your doctor or pharmacist if you are not sure.

All doses are worked out depending on the child's age, bodyweight in kilograms, kidney function and type and severity of infection. Your doctor will advise you how much **CO-AMOXICLAV UNIMED** you should give to your baby or child.

CO-AMOXICLAV S UNIMED:
The usual dose is as follows:
Children weighing 13-21 kg (2-6 years): 5-10 ml (1-2 medicine teaspoons), three times a day.

CO-AMOXICLAV SF UNIMED:
The usual dose is as follows:
Children weighing 22-40 kg (7-12 years): 5-10 ml (1-2 medicine teaspoons), three times a day.

Patients with kidney and liver problems

If your child has kidney problems the dose might be changed and chosen by your doctor based on kidney function.

Your doctor will tell you how long treatment with CO-AMOXICLAV UNIMED will last. Do not stop treatment early. If you have the impression that the effect of CO-AMOXICLAV UNIMED is too strong or too weak, tell your doctor or pharmacist.

How to give CO-AMOXICLAV UNIMED

- Shake the bottle well before each use.
- Give the medicine immediately before a meal.
- Do not give CO-AMOXICLAV UNIMED for more than 2 weeks. If your child still feels unwell you should go back to see the doctor.
- For information on how to prepare (reconstitute) the medicine, see *'Contents of the pack and other information'* in section 6.

If you give more CO-AMOXICLAV UNIMED than you should

If you give too much CO-AMOXICLAV UNIMED, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions. If your child suffers from kidney disease and you notice anything unusual with the urine (intense burning, or red blood cells in your urine) get medical help immediately. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to give CO-AMOXICLAV UNIMED

- If you forget to give a dose, give it as soon as you remember.
- Do not give a double dose to make up for forgotten individual doses.

If you stop giving CO-AMOXICLAV UNIMED

Keep giving CO-AMOXICLAV UNIMED until the treatment is finished, even if your child feels better. Your child needs every dose to help fight the infection. If some bacteria survive, they can cause the infection to come back and make the medicine less effective due to resistance. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

CO-AMOXICLAV UNIMED can have side effects.
Not all side effects reported for CO-AMOXICLAV UNIMED are included in this leaflet.
Should your child's general health worsen or if your child experiences any untoward effects while taking CO-AMOXICLAV UNIMED, please consult your health care provider for advice.

If any of the following happens, STOP giving CO-AMOXICLAV UNIMED and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- dizziness or collapse
- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome)
- inflammation of the large intestine, causing watery diarrhoea usually with blood and mucus, stomach pain and/or fever

These are all very serious side effects. If your child has them, they may have had a serious reaction to CO-AMOXICLAV UNIMED. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- thrush (candida - a yeast infection of the vagina, mouth or skin folds)
- feeling sick (nausea), especially when taking high doses
- being sick (vomiting)
- diarrhoea

Less frequent side effects:

- skin rash
- raised itchy rash (hives)
- indigestion or abdominal pain
- dizziness
- headache
- increase in some substances (enzymes) produced by the liver
- severe reduction in the number of white blood cells (leukopenia)
- low number of red blood cells (haemolytic anaemia)

Side effects of which frequency is not known:

- allergic reactions (see above)

- inflammation of the large intestine (see above)
- inflammation of the protective membrane surrounding the brain (aseptic meningitis)
- serious skin reactions:
  - a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), and a more severe form, causing extensive peeling of the skin (more than 30% of the body surface – toxic epidermal necrolysis)
  - widespread red skin rash with small pus-containing blisters (bullous exfoliative dermatitis)
  - a red, scaly rash with bumps under the skin and blisters (exanthemous pustulosis)
  - flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))
- inflammation of the liver (hepatitis)
- jaundice, caused by increases in the blood of bilirubin (a substance produced in the liver) which may make your skin and whites of the eyes appear yellow
- inflammation of tubes in the kidney
- blood takes longer to clot
- hyperactivity
- convulsions (in people taking high doses of CO-AMOXICLAV UNIMED or who have kidney problems)
- black tongue which looks hairy
- acute inflammation of the pancreas (acute pancreatitis). If you have severe and on-going pain in the stomach area this could be a sign of acute pancreatitis.
- Drug-induced enterocolitis syndrome (DIES) has been reported mainly in children receiving amoxicillin/clavulanate. It is a certain kind of allergic reaction with the leading symptom of repetitive vomiting (1-4 hours after medicine intake). Further symptoms could comprise abdominal pain, lethargy, diarrhoea and low blood pressure.
- crystals in urine leading to acute kidney injury
- rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)

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. 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/Publications/Index/8.
By reporting side effects, you can help provide more information on the safety of **CO-AMOXICLAV UNIMED**.

5. How to store CO-AMOXICLAV UNIMED

Store all medicines out of reach of children.

Dry powder: Store in original container at or below 30 ºC.

Do not use this medicine after the expiry date (EXP) which is stated on the bottle.

The expiry date refers to the last day of that month.

Liquid suspension: Store at 2 °C – 8 °C in a refrigerator. Do not freeze. Once made up, the suspension should be used within 7 days.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CO-AMOXICLAV UNIMED contains

CO-AMOXICLAV S UNIMED:

The active substances are amoxicillin 125 mg (as amoxicillin trihydrate) and clavulanic acid 31,25 mg (as potassium clavulanate).

CO-AMOXICLAV SF UNIMED:

The active substances are amoxicillin 250 mg (as amoxicillin trihydrate) and clavulanic acid 62,5 mg (as potassium clavulanate).

The other ingredients are silica colloidal anhydrous, succinic acid, hypromellose, xanthan gum, strawberry guarana flavour, silicon dioxide and aspartame (see ***'CO-AMOXICLAV UNIMED contains aspartame'*** in section 2).

What CO-AMOXICLAV UNIMED looks like and contents of the pack

CO-AMOXICLAV S UNIMED is a white to off-white granular powder supplied in a translucent plastic bottle. Once made up, the bottle contains 100 ml of a white to off white strawberry flavoured suspension.

For reconstitution to 100 ml, first shake bottle to loosen powder, add 92 ml water, invert bottle and shake well until all the powder is dispersed.

CO-AMOXICLAV SF UNIMED is a white to off-white granular powder supplied in a translucent plastic bottle. Once made up, the bottle contains 100 ml of a white to off white strawberry flavoured suspension.

For reconstitution to 100 ml, first shake bottle to loosen powder, add 90 ml water, invert bottle and shake well until all the powder is dispersed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Please visit https://unimedhealthcare.co.za