

1. NAME OF THE MEDICINAL PRODUCT

CO MAUG 1 g (Amoxicillin/Clavulanic acid 875 mg/125 mg, Film-coated tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains amoxicillin trihydrate equivalent to 875 mg amoxicillin and potassium clavulanate equivalent to 125 mg clavulanic acid.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablets.

The white to off white 22 mm by 10 mm oblong film-coated tablets with score line. Score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4. CLINICAL PARTICULARS**4.1 Therapeutic indications**

- CO MAUG 1 g is indicated for adults for the treatment of the following infections caused by amoxicillin-resistant organisms producing β -lactamases sensitive to clavulanic acid (see section 4.2, section 4.4 and section 5.1):
- Upper respiratory tract infections - such as sinusitis, recurrent otitis media, tonsillitis
 - Lower respiratory tract infections - such as bronchitis and bronchopneumonia
 - Genito-urinary tract infections - such as cystitis, urethritis, proctonephritis
 - Skin and soft tissue infections

CO MAUG 1 g formulations will also be effective in the treatment of infections caused by amoxicillin-sensitive organisms at the appropriate amoxicillin dosage since in this situation the clavulanic acid component does not contribute to the therapeutic effect.

4.2 Posology and method of administration**Posology**

During the administration of amoxicillin, it is advisable to maintain adequate fluid intake and urinary output in order to prevent any possibility of amoxicillin crystalluria.

General information: For infections caused by amoxicillin-sensitive organisms the dosage is that approved for amoxicillin as the clavulanic acid component does not contribute to the therapeutic effect.

Adults:
For severe infections, one CO MAUG 1 g tablet every 12 hours at the start of a meal.

Special populations**Impaired renal function:**

Both amoxicillin and clavulanic acid are excreted by the kidneys and the serum half-life of each increases in patients with renal failure. Therefore, the dose may need to be reduced or the interval extended. Dosage adjustments are based on the maximum recommended level of amoxicillin.

CO MAUG 1 g should not be used in patients with a glomerular filtration rate of less than 30 ml/min. However, dose reduction is not necessary in patients with renal impairment and clavulanic acid and an additional dose should be administered at the end of dialysis.

Elderly:
No dose adjustment is considered necessary.

Hepatic impairment:

Dose with caution and monitor hepatic function at regular intervals (see section 4.3 and section 4.4).

Method of administration

CO MAUG 1 g is for oral use.

Tablets should be taken immediately before a meal.

Dosage Guide:**Amoxicillin-Sensitive Organisms**

Upper respiratory tract infections	Lower respiratory tract infections	Urinary tract infections	Skin and soft tissue infections
1 tablet 12-hourly	1 tablet 12-hourly	1 tablet 12-hourly	1 tablet 12-hourly

Amoxicillin-Resistant Organisms:

Upper respiratory tract infections (Otitis media)	Lower respiratory tract infections (Otitis media)	Urinary tract infections	Skin and soft tissue infections
<i>H. influenzae</i> , <i>H. parainfluenzae</i>	<i>H. influenzae</i> , <i>H. parainfluenzae</i>	<i>Methicillin sensitive Klebsiella pneumoniae</i>	<i>Methicillin sensitive Staphylococcus aureus</i>

Adults:

1 tablet 12-hourly	1 tablet 12-hourly	1 tablet 12-hourly	1 tablet 12-hourly
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4.3 Contraindications

CO MAUG 1 g is contraindicated in:

- Hypersensitivity to the active substances amoxicillin or clavulanic acid or to any of the excipients (see section 6.1).
- Hypersensitivity to penicillins or to cephalosporins. Cross-sensitivity between penicillins and cephalosporins is well documented.
- CO MAUG 1 g is contraindicated in patients with a previous history of amoxicillin/clavulanic-associated jaundice/hepatic dysfunction (see section 4.8).

4.4 Special warnings and precautions for use

Prescribers must adhere to the principles of antibiotic stewardship. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients on amoxicillin therapy. Before initiating therapy with CO MAUG 1 g, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other allergens. Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral penicillins. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and/or a history of sensitivity to multiple allergens. There have been reports of individuals with a history of penicillin hypersensitivity, who have experienced severe reactions when treated with amoxicillin. If an allergic reaction occurs, CO MAUG 1 g should be discontinued and the appropriate therapy instituted. Serious anaphylactic reactions may require immediate emergency treatment with adrenaline. Oxygen, intravenous steroids and airway management, including intubation may also be required.

Severe cutaneous adverse reactions (SCAR), such as Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalised exanthematous pustulosis (AGEP) have been reported in patients taking beta-lactam antibiotics. When SCAR is suspected, beta-lactam antibiotics should be discontinued.

In the case that an infection is proven to be due to an amoxicillin-susceptible organism(s) then consideration should be given to switching from amoxicillin/clavulanic acid to amoxicillin.

CO MAUG 1 g is not suitable for use when there is a high risk that the presumptive pathogens have resistance to beta-lactam agents that is not mediated by beta-lactamases susceptible to inhibition by clavulanic acid. CO MAUG 1 g should not be used to treat penicillin-resistant *S. pneumoniae*.

CO MAUG 1 g should be avoided if infectious mononucleosis is suspected since the occurrence of a full list of excipients in less frequent circumstances, deaths have been reported. These have almost always occurred in patients with serious underlying disease or taking concomitant medications known to have the potential for hepatic effects (see section 4.8).

Prolonged use may result in overgrowth of non-susceptible organisms. *Pseudomonas aeruginosa* has been reported.

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

The occurrence at the treatment initiation of a feverish generalised erythema associated with pustula may be a symptom of acute generalised exanthematous pustulosis (AGEP) (see section 4.8). This reaction is important to consider in patients who present with diarrhoea following the administration of amoxicillin. requires CO MAUG 1 g discontinuation and contraindications any subsequent administration of amoxicillin.

Prolongation of prothrombin time has been reported rarely in patients receiving CO MAUG 1 g. Appropriate monitoring should be undertaken when anticoagulants are prescribed concurrently.

Antibiotic-associated colitis (including pseudomonas colitis, haemorrhagic colitis *Clostridium difficile* associated diarrhoea (CDAD)), has been reported with nearly all antibiomatic agents including amoxicillin and may range in severity from mild to life threatening (see section 4.8). Therefore, it is important to consider this diagnosis in patients who present with diarrhoea following the administration of any antibiotics. Should antibiotic-associated colitis occur, CO MAUG 1 g should immediately be discontinued, a medical practitioner be consulted and an appropriate therapy initiated. Periodic medical products are contraindicated in this situation.

Caution is needed when administering amoxicillin to patients with syphilis, as the Jarisch-Herxheimer reaction may occur in these patients.

When high doses are administered, adequate fluid intake and urinary output must be maintained.

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

CO MAUG 1 g should be given with caution to patients with lymphatic leukaemia since they are especially susceptible to amoxicillin-induced skin rashes.

Periodic assessment of organ function, including renal, hepatic and haematopoietic functions, is advisable during prolonged therapy.

Impaired hepatic function: Changes in liver function tests have been observed in some patients receiving CO MAUG 1 g. Transient hepatitis and cholestatic jaundice have been reported. CO MAUG 1 g should be discontinued in patients with evidence of hepatic dysfunction.

Hepatic events have been reported predominantly in males and elderly patients and may be associated with symptoms of acute generalised exanthematous pustulosis (AGEP) (see section 4.8). This reaction is important to consider in patients who present with diarrhoea following the administration of any antibiotics. Should antibiotic-associated colitis occur, CO MAUG 1 g should immediately be discontinued, a medical practitioner be consulted and an appropriate therapy initiated. Periodic medical products are contraindicated in this situation.

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1. NAAM VAN DIE GENEESEMIDDEL

CO MAUG 1 g (Amoksilliën/Klavulaansuur 875 mg/125 mg, Filmbedekte tablette)

2. KWALITATIEWE EN KWANTITATIEWE KOMPOSISIE

Eike filmbedekte tablette bevat amoksilliën/trihidraat gelyk aan 875 mg amoksilliën en klavulaansuur gelyk aan 125 mg klavulaansuur.

Sien afdeling 6.1 vir volledige lys van bysaamwese.

3. FARMASEUTIESE VORM

Filmbedekte tablette.

Wit tot afwit 22 mm by 10 mm langwerpige filmbedekte tablette met inkeping. Die inkeping is slegs om breek te vergemaklik vir die gemak van sluk en nie in gelyke dosisse te verdeel nie.

4. KLINIÏESE BESONDERHEDE**4.1 Terapeutiese indikasies**

- CO MAUG 1 g word aangewend vir volwessenes vir die behandeling van die volgende infeksies wat deur amoksilliën-veerstandige organismes veroorsaak word deur β -laktamases produseer wat sensitief is vir klavulaansuur (sien afdeling 4.2, afdeling 4.4 en afdeling 5.1):
- Boonste lugweginfeksies - soos sinusitis, herhalende otitis media, mangelontsteking
 - Laer lugweginfeksies - soos bronchitis en bronchopneumonie
 - Genitourinêre infeksies - soos sistitis, uretrië, proctonephritis
 - Skin- en sagteweefselinfeksies

CO MAUG 1 g formulering sal ook doeltreffend wees in die behandeling van infeksies veroorsaak deur amoksilliën-sensitiewe organismes teen die passie amoksilliëndosis, omdat klavulaansuur in hierdie situasie nie tot die terapeutiese uitwerking bydra nie.

4.2 Posologie en metode van toediening**Posologie**

Die dosering van amoksilliën is dit basisskaal om voldoende woiestofname en urineëre uitsekding te onderhou om die moontlikheid van amoksilliën-kristallurie te voorkom.

Algemene inligting: Vir infeksies wat deur amoksilliën-sensitiewe organismes veroorsaak is, is die dosis die soos vir amoksilliën goedgekeur, aangesien die komponent van klavulaansuur nie bydra tot die terapeutiese effek nie.

Volwessenes:
Vir ernstige infeksies, een CO MAUG 1 g tablet elke 12 ure voor 'n maaltyd.

Spesiale populasies**Ingekorste nierfunksie:**

Beigingsvlakke van klavulaansuur word uitgeskei deur die niere en die serumhalflewydte van elk neem toe by pasiënte met nierversaking. Dus kan dit nodig wees om die dosis te verminder of die interval te verleng. Dossiaangepassings is gebaseer op die maksimum aanbevole vlak vir amoksilliën.

CO MAUG 1 g moet nie gebruik word by pasiënte met 'n glomerulêre filtratiese tempo van minder as 30 ml/minuut nie.

Hemodialise verminder serumkonentrasies van beide amoksilliën en klavulaansuur en 'n bykomende dosis moet aan die einde van dialise toegedien word.

Bejaardes:
Geen dosis verandering word as noodsaaklik beskou.

Hepatiese inkorning:

Doseer met omsigtigheid en monitor die lewerfunksie met gereelde tussenposes (sien afdeling 4.3 en 4.4).

Metode van toediening

CO MAUG 1 g is vir orale gebruik.

Tablette moet onmiddellik voor die geneem word.

Doseringsgids:**Amoksilliën-Sensitiewe Organismes**

Boonste lugweginfeksies (Otitis media)	Onderste lugweginfeksies	Urieërweginfeksies	Vel- en sagteweefselinfeksies
1 tablet 12-uurlik	1 tablet 12-uurlik	1 tablet 12-uurlik	1 tablet 12-uurlik

Amoksilliën-Weerstandige Organismes:

Boonste lugweginfeksies (Otitis media)	Onderste lugweginfeksies	Urieërweginfeksies	Vel- en sagteweefselinfeksies
<i>H. influenzae</i> , <i>H. parainfluenzae</i>	<i>H. influenzae</i> , <i>H. parainfluenzae</i>	<i>E. coli</i> , <i>Klebsiella pneumoniae</i>	<i>Methicillin-sensitiewe Staphylococcus aureus</i>

Volwessenes:

1 tablet 12-uurlik	1 tablet 12-uurlik	1 tablet 12-uurlik	1 tablet 12-uurlik
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4.3 Kontraindikasies

CO MAUG 1 g is teenaangewend in:

- Hypersensitiewe reaksies teen die aktiewe stowwe amoksilliën of klavulaansuur of vir enige van die hulpstowwe (sien afdeling 6.1).
- Hipersensitiewe vir penisilliene of kiefalosporiene. Kruis-sensitiewe tussen penisilliene en kiefalosporiene is goed gedokumenteer.
- CO MAUG 1 g is teenaangewend by pasiënte met 'n vorige geskiedenis van amoksilliën/klavulaansuur-gevoelende geelings/hepatiese disfunksie (sien afdeling 4.8).

4.4 Spesiale waarskuldigings en voorsorgmaatreëls vir gebruik

Voorskrywers moet die beginsels van antibiotika-terapiebestuursprak nasien. Ernstige en soms noodlottige hipersensitiewe reaksies (anafilaktiese reaksies) is aangemeld by pasiënte wat penisillien-terapie ondergaan. Deeglike navrae aangaande vorige hipersensitiewe reaksies teen oral penisilliene, kiefalosporiene of ander allergene moet gedoen word, alvorens behandeling met CO MAUG 1 g salving te begin. Hoewel analities meer dikwels voorkom na parenterale terapie, het dit voorkom by pasiënte op mondelike penisilliene. Hierdie reaksies is meer geneig om voor te kom by individue met 'n geskiedenis van penisillien-hipersensitiewe of 'n geskiedenis van sensitiewe reaksie teen ander wettige allergene. Daar is verskeie gevalle van individue met 'n geskiedenis van penisillien-hipersensitiewe, wat ernstige reaksies ervaar het as hulle met amoksilliën behandel is.

As allergiese reaksie plaasvind, moet CO MAUG 1 g gestaak word en moet die geskikte terapie begin word (Reaksie Reponering Form) wat aan 'n mediese persoonlike behandeling met 'n adrenaleen benodig. Suurstof, intraveniese steroïede en bestuur van die lugweg, insluitend intubasie, mag ook benodig word.

Ernstige kutane newe-effekte (SCAR), soos Stevens-Johnson-sindroom (SJS), toksiese epidermale nekrolise (TEN), genesemiddelreaksie met eosinofiele en sistemiese simptome (DRESS) en akute veralgemeende eksantematiese pustulose (AGEP) is gerapporteer by pasiënte wat beta-laktam antibiotika behandel is. As SCAR vermoed word, moet beta-laktam-antibiotika gestaak word.

In die geval dat dit bewys word dat 'n infeksie te wyle is aan 'n amoksilliën-voorbereiding, moet dit oorweeg word om oorskakel van amoksilliën/klavulaansuur na amoksilliën te doen.

CO MAUG 1 g is nie geskik vir gebruik as daar 'n groot risiko bestaan dat die veronderstelde patogeen weerstandig is teen beta-laktam-middels wat nie bemiddel word deur beta-laktamases wat verbaar tot inhibisie deur klavulaansuur is nie. CO MAUG 1 g moet nie gebruik word vir die behandeling van penisillien-veerstandige *S. pneumoniae* nie.

CO MAUG 1 g moet vermy word indien aansteeklike mononukleose vermoed word, aangesien die voorkoms van 'n morbillivormige uitslag met die toestand geassocieer is in die gebruik van amoksilliën.

Konvulsies kan voorkom by pasiënte met ingekorste nierfunksie of by die wat hoë dosisse ontvang (sien afdeling 4.8)

Verlengde gebruik mag lei tot oorgroei van nie-ge