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APPROVED
Samantha , 14:42:55, 02/14/2022

AURO-AMOXICLAV
P1529121

AURO-AMOXICLAV
P1529121

SKEDULERINGSTATUS:
Suid-Afrika: **S4**
Namibië: **NS2**

EIENDOMSNAAM (en doseervorm):
AURO-AMOXICLAV 125-31,25 mg/5 ml (Poeier vir orale suspensie)
AURO-AMOXICLAV 250-62,5 mg/5 ml (Poeier vir orale suspensie)

SAMESTELLING:
AURO-AMOXICLAV 125-31,25 mg/5 ml:
Elke 5 ml (na hersamestelling) bevat: amoksisillientrihidraat ekwivalent aan amoksisillien 125 mg en kaliumklavulanaat ekwivalent aan 31,25 mg klavulaansuur. Suikervry. Bevat versoeter: 5 mg aspartaam per 5 ml.
AURO-AMOXICLAV 250-62,5 mg/5 ml:
Elke 5 ml (na hersamestelling) bevat: amoksisillientrihidraat ekwivalent aan amoksisillien 250 mg en kaliumklavulanaat ekwivalent aan 62,5 mg klavulaansuur. Suikervry. Bevat versoeter: 10 mg aspartaam per 5 ml.
Lys van bymiddels:
Aspartaam, hipromellose, kolloïdaleanhidriesesilika, silikondioksied, aarbei-guaranasmaakmiddel, suksinielsuur en xantaangom.

FARMAKOLOGIESE KLASSIFIKASIE:
A 20.1.2 Penisilliene

FARMAKOLOGIESE WERKING:
AURO-AMOXICLAV is 'n kombinasie van amoksisillien en klavulaansuur.
Amoksisillien is 'n semi-sintetiese beta-laktamase vatbare penisillien wat *in vitro* bakteriedodende aktiwiteit teen 'n wye spektrum van nie-laktamaseproduserende Gram-positiewe en Gram-negatiewe organismes besit. Die spektrum van aktiwiteit sluit nie daardie organismes in wat beta-laktamases produseer nie, nl. weerstandbiedende stafilokokke en al die stamme van *Pseudomonas, Klebsiella* en *Enterobacter.*
In vitro is dit aangetoon dat klavulaansuur 'n onomkeerbare inhibeerder van beta-laktamases is wat deur die volgende organismes geproduseer word: *Staphylococcus aureus, Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Haemophilus influenzae, Neisseria gonorrhoea* en *Bacteroides fragilis.* Klavulaansuur inaktiveer nie die chromosomaalgemedieerde (Sykes Tipe 1 kefalosporinase) beta-laktamases wat deur die volgende organismes geproduseer word nie: *Acinetobacter* spesies, *Citrobacter* spesies, *Enterobacter,* indool positiewe *Proteus, Providencia* spesies en *Serratia marcescens. In vitro* toon die formulasie sinergisme teen amoksisillien- weerstandbiedende organismes, met geen bewys van antagonisme nie, en die aktiwiteit is nie deur die teenwoordigheid van serum verminder nie.
(*In vitro* aktiwiteit beteken nie noodwendig *in vivo* doeltreffendheid nie).

Farmakokinetika:
Absorpsie:
Amoksisillien is stabiel in die teenwoordigheid van suur maagsekresies. Piek bloedvlakke word binne 1 – 2 ure na toediening bereik. Daar bestaan 'n lineêre dosisrespons in piek serumvlakke.
Die farmakokinetika van amoksisillien en klavulaansuur is nou verwant en nie een van die middels word nadelig deur die teenwoordigheid van voedsel in die maag beïnvloed nie.
Verspreiding:
Ongeveer 18 % van die totale hoeveelheid amoksisillien in plasma is proteïengebonde. Amoksisillien versprei maklik na die meeste liggaamsweefsels, behalwe die brein en serebrospinale vloeistof. Oor die algemeen verhoog inflammasie die deurlaatbaarheid van die meninges tot penisilliene en dit mag ook op amoksisillien van toepassing wees.
Uitskeiding:
Die eliminasiehalfleeftyd van amoksisillien is ongeveer 1 uur. Klein hoeveelhede amoksisillien word ook in die feses en gal uitgeskei.

INDIKASIES:
AURO-AMOXICLAV formulasies word aangedui vir die behandeling van infeksies veroorsaak deur amoksisillien-weerstandbiedende organismes wat beta-laktamases produseer, wat sensitief teen klavulaansuur is:
Boonste lugweginfeksies soos sinusitis, herhalende otitis media en tonsilitis.
Onderste lugweginfeksies soos brongitis en brongopneumonie.
Genito-urienweginfeksies soos sistitis, uretritis en piëlonefritis.
Infeksies van die vel en sagteweefsel.
AURO-AMOXICLAV formulasies sal ook doeltreffend in die behandeling van infeksies veroorsaak deur amoksisilliensensitiewe organismes met die toepaslike amoksisilliendosis wees, aangesien die klavulaansuur komponent in hierdie geval nie tot die terapeutiese effek bydra nie.

KONTRA-INDIKASIES:
Hipersensitiwiteit teen penisilliene of kefalosporiene. Kruissensitiwiteit tussen penisilliene en kefalosporiene is deeglik gedokumenteer.
AURO-AMOXICLAV word teenaangedui in pasiënte met 'n vorige geskiedenis van amoksisillien/klavulaansuur verwante geelsug/lewer disfunksie.

WAARSKUWINGS EN SPESIALE VOORSORGSMAATREËLS:
Ernstige en soms fatale hipersensitiwiteitsreaksies (anafilakties) is aangemeld in pasiënte op penisillienterapie. Voordat daar met **AURO-AMOXICLAV** terapie begin word, behoort noukeurige navraag gedoen te word ten opsigte van vorige hipersensitiwiteitsreaksies teen penisillien, kefalosporiene of ander allergene. Alhoewel anafilakse meer dikwels na parenterale terapie voorkom, het dit in pasiënte op orale penisillien al voorgekom. Hierdie reaksies sal meer waarskynlik in indiwidue voorkom met 'n geskiedenis van hipersensitiwiteit teen penisilliene en/of 'n geskiedenis van sensitiwiteit teen veelvuldige allergene. Daar bestaan vermeldings van indiwidue met 'n geskiedenis van hipersensitiwiteit teen penisilliene wat erge reaksies getoon het nadat hulle met kefalosporiene behandel is.
Indien 'n allergiese reaksie voorkom, behoort **AURO-AMOXICLAV** gestaak en die toepaslike terapie ingestel te word. Ernstige anafilaktiese reaksies mag onmiddellike noodbehandeling met adrenalien vereis. Suurstof, intraveneuse kortikosteroïede en lugwegbestuur, insluitende intubering, mag ook nodig wees.
AURO-AMOXICLAV behoort vermy te word indien besmetlike mononukleose vermoed word aangesien die voorkoms van 'n morbillivormE uitslag na die gebruik van amoksisillien met hierdie kondisie geassosieer word.
Verlengde gebruik mag tot oorgroeiing van nie-vatbare organismes lei. Pseudomembraneuse enterokolitis is aangemeld.
Verlenging van die protrombientyd is af en toe in pasiënte wat **AURO-AMOXICLAV** ontvang het, aangemeld.
Toepaslike monitering behoort uitgevoer te word wanneer antistolmiddels gelyktydiglik voorgeskryf word.
Periodieke evaluering van orgaanfunksie, insluitende nier-, lewer- en hematopoïetiese funksies word gedurende verlengde terapie aanbeveel.
Verbygaande hepatitis en cholestatiese geelsug is aangemeld. **AURO-AMOXICLAV** behoort met sorg gebruik te word in pasiënte met bewyse van lewerdisfunksie.

Sorg moet aan die dag gelê word wanneer **AURO-AMOXICLAV** aan pasiënte met sifilis toegedien word, aangesien die Jarisch-Herxheimer reaksie in hierdie pasiënte mag voorkom.

Wanneer hoë dosisse toegedien word, moet 'n hoë vloeistofinname en urienuitset onderhou word.
Aangesien **AURO-AMOXICLAV** amoksisillien, 'n aminopenisillien bevat, is dit nie die behandeling van keuse in pasiënte wat met 'n seer keel of faringitis presenteer nie, aangesien die onderliggende oorsaak besmetlike mononukleose mag wees. Met laasgenoemde is daar 'n hoë insidens van veluitslag wanneer amoksisillien gebruik word. **AURO-AMOXICLAV** behoort met sorg toegedien te word aan pasiënte met limfatiese leukemie, aangesien hulle veral vatbaar vir amoksisillien geïnduserde veluitslag is.
Die moontlikheid van superinfeksies met mikotiese of bakteriese patogene behoort gedurende terapie in gedagte gehou te word. Indien superinfeksies voorkom (waarby *Aerobacter, Pseudomonas* of *Candida* gewoonlik betrokke is), behoort die gebruik van die middel gestaak en/of toepaslike terapie ingestel te word.

Belemmerde lewerfunksie:
Veranderinge in lewerfunksietoetse is waargeneem in sommige pasiënte wat **AURO-AMOXICLAV** ontvang het. Dit behoort met sorg in pasiënte met bewyse van ernstige lewer disfunksie gebruik te word.

Belemmerde nierfunksie:
In pasiënte met matig tot erg belemmerde nierfunksie behoort die dosis van **AURO-AMOXICLAV** aangepas te word (sien "**DOSIS EN GEBRUIKSAANWYSINGS**").

Gebruik in laktasie:
Amoksisillien word in die melk uitgeskei; daar bestaan egter geen data oor die uitskeiding van klavulaansuur in moedersmelk nie. Daarom behoort sorg aan die dag gelê te word wanneer **AURO-AMOXICLAV** aan borsvoedende moeders toegedien word.

Die gebruik van **AURO-AMOXICLAV** mag tot die seleksie van weerstandbiedende stamme van organismes lei en sensitiwiteits toetsing behoort daarom, wanneer moontlik, uitgevoer te word om die toepaslikheid van terapie aan te toon.

INTERAKSIES:
AURO-AMOXICLAV mag die doeltreffendheid van orale voorbehoedmiddels verminder en pasiënte behoort dienooreenkomstig gewaarsku te word.
Die gelyktydige toediening van allopurinol saam met **AURO-AMOXICLAV** verhoog die insidens van veluitslag aansienlik in pasiënte wat beide middels gebruik in teenstelling met pasiënte wat ampisillien alleen gebruik. Dit is nie bekend of hierdie potensiëring van ampisillien uitslag die gevolg van allopurinol is nie, en of dit die hiperurisemie is wat in hierdie pasiënte teenwoordig is.
Tetrasikliene en ander bakteriostatiese middels mag met die bakteriedodende effekte van amoksisillien inmeng.

Interaksie met laboratoriumtoetse:
Daar word aanbeveel dat wanneer daar vir die teenwoordigheid van glukose in urien gedurende **AURO-AMOXICLAV** behandeling getoets word, ensimatiese glukose-oksidasemetodes gebruik moet word. Weens die hoë amoksisillien konsentrasies in urien, kom vals positiewe resultate dikwels met chemiese toetsing voor.

SWANGERSKAP EN LAKTASIE:
Gebruik gedurende swangerskap:
Die veiligheid van **AURO-AMOXICLAV** gedurende swangerskap is nie vasgestel nie.

Gebruik gedurende laktasie:
Amoksisillien word na moedersmelk versprei. Alhoewel noemenswaardige probleme nie in mense gedokumenteer is nie, mag die gebruik van **AURO-AMOXICLAV** deur borsvoedende moeders tot sensitering, diarree, kandidiase en veluitslag in die baba lei.

DOSIS EN GEBRUIKSAANWYSINGS:
Gebruiksaanwysings vir hersamestelling:
AURO-AMOXICLAV 125-31,25 mg/5 ml:
Vir hersamestelling tot 100 ml, voeg 92 ml water by, keer die bottel om en skud goed totdat die poeier opgelos is.
AURO-AMOXICLAV 250-62,5 mg/5 ml:
Vir hersamestelling tot 100 ml, voeg 90 ml water by, keer die bottel om en skud goed totdat die poeier opgelos is.
AURO-AMOXICLAV suspensie mag onmiddellik voor 'n maaltyd geneem word.
Dosis:
Algemene inligting: Vir infeksies veroorsaak deur amoksisillien sensitiewe organismes is die dosis soos goedgekeur vir amoksisillien aangesien die klavulaansuur komponent nie tot die terapeutiese effek bydra nie.
Kinders:
Die **AURO-AMOXICLAV** dosis in kinders is 25-50 mg/kg/dag van die 4 dele amoksisillien, 1 deel klavulaansuur preparate (wat ooreenstem met 20–40 mg/kg amoksisillien en 5–10 mg/kg klavulaansuur), geneem in verdeelde dosisse, elke 8 ure met die begin van 'n maaltyd.
Doseringsgids:

Amoksisillien Sensitiewe Organismes

Produk	Boonste lugweginfeksies	Onderste lugweginfeksies	Urienweg-infeksies	Infeksies van die vel en sagteweefsel
AURO-AMOXICLAV 125-31,25 mg/5 ml (9-18 kg)	5-10 ml* elke 8 ure	5-10 ml* elke 8 ure	5-10 ml* elke 8 ure	5-10 ml* elke 8 ure
AURO-AMOXICLAV 250-62,5 mg/5 ml (18–37 kg)	5 ml* elke 8 ure	5 ml* elke 8 ure	5 ml* elke 8 ure	5 ml* elke 8 ure

Amoksisillien Weerstandbiedende Organismes

Produk	Boonste lugweginfeksies (Otitis media)	Onderste lugweginfeksies (Brongitis)	Urienweg-infeksies	Infeksies van die vel en sagteweefsel
AURO-AMOXICLAV 125-31,25 mg/5 ml (9-18 kg)	5-10 ml^ elke 8 ure	5-10 ml* elke 8 ure	5-10 ml* elke 8 ure	5-10 ml* elke 8 ure
AURO-AMOXICLAV 250-62,5 mg/5 ml (18–37 kg)	5-10 ml^ elke 8 ure	5-10 ml* elke 8 ure	5-10 ml* elke 8 ure	5-10 ml* elke 8 ure

*Om ooreen te stem met ‘n dosis van 25-50 mg/kg/dag.
^Om ooreen te stem met ‘n dosis van 50 mg/kg/dag.

NEWE EFFEKTE:
Die insidens en graad van erns van newe effekte, veral naarheid en diarree, het met die hoër aanbevole dosis toegeneem en kan beperk word deur **AURO-AMOXICLAV** aan die begin van 'n maaltyd toe te dien. Boonop, aangesien hierdie simptome veral verband hou met die kaliumklavulanaat komponent, waar hierdie gastroïntestinale simptome voorkom en 'n hoër konsentrasie amoksisillien vereis word, behoort oorweging aan die toediening van addisionele amoksisillien apart, gegee te word.

Die volgende newe effekte is aangemeld en mag met die gebruik van **AURO-AMOXICLAV** voorkom:
Afwykings van die immuunsisteem:
Dikwels:
Veluitslag, pruritus en urtikarie, serumsiekte-agtige sindroom, erythema multiforme, Stevens-Johnson se sindroom en toksiese epidermale nekrolise is aangemeld. Wanneer sulke reaksies voorkom, behoort **AURO-AMOXICLAV** gestaak te word. Ernstige en soms fatale hipersensitiwiteits reaksies (anafilakties) en angioneurotiese edeem kan met orale penisillien voorkom (sien "**WAARSKUWINGS EN SPESIALE VOORSORGSMAATREËLS**").
Die volgende newe effekte is aangemeld en die frekwensie is onbekend:
Hipersensitiwiteits vaskulitis en bulleuse eksfoliatiewe dermatitis. Wanneer sulke reaksies voorkom, behoort **AURO-AMOXICLAV** gestaak te word.
Interstisiële nefritis mag voorkom.

Gastroïntestinale afwykings:
Baie dikwels:
Naarheid, braking, diarree.
Dikwels:
Glossitis.
Die volgende newe effekte is aangemeld en die frekwensie is onbekend:
Indigestie, buikpyn, gastritis, stomatitis, swart “harige” tong, enterokolitis, mukokutane kandidiase en antibiotika verwante kolitis (insluitende pseudomembraneuse kolitis en bloederige kolitis) en abnormale smaak. Oppervlakkige tandverkleuring is aangemeld, veral met die suspensie formulasies. Dit kan gewoonlik verwyder word deur die tande te borsel.
Indien tekens van gastroïntestinale reaksies voorkom, kan dit verminder word deur **AURO-AMOXICLAV** aan die begin van 'n maaltyd te neem.

Hepato-biliêre afwykings:
Dikwels:
Hepatitis en cholestatiese geelsug is aangemeld. Hierdie gebeure mag erg wees en kom hoofsaaklik in volwassenes en bejaardes voor. Tekens en simptome kom gewoonlik gedurende of kort na behandeling voor. In sommige gevalle mag dit egter eers verskeie weke nadat behandeling gestaak is, voorkom. Die hepatiese effekte is gewoonlik omkeerbaar. In die uiterste gevalle is dood aangemeld. Dit was byna altyd gevalle wat met ernstige onderliggende siekte of die wat ander medikasie gelyktydig geneem het. 'n Matige toename in aspartaattransaminase (AST) en/of alanientransaminase (ALT) is waargeneem in pasiënte wat met **AURO-AMOXICLAV** behandel is.

Nier- en urienafwykings:
Die volgende newe effekte is aangemeld en die frekwensie is onbekend:
Kristalurie.

Geslagstelsel- en borsafwykings:
Die volgende newe effekte is aangemeld en die frekwensie is onbekend:
Vaginitis.

Afwykings van die bloed en limfsisteem:
Dikwels:
Omkeerbare trombositopenie, trombositopeniese purpura, en omkeerbare leukopenie is aangemeld. Hierdie reaksies is gewoonlik omkeerbaar met staking van terapie en daar word vermoed dat dit 'n hipersensitiwiteits fenomeen is. 'n Ligte trombositose is in minder as 1 % van pasiënte waargeneem wat met **AURO-AMOXICLAV** behandel is. Verlenging van bloedings- en protrombientyd is ook dikwels aangemeld. Toepaslike monitering behoort toegepas te word wanneer teenstolmiddels tegelykertyd voorgeskryf word.
Die volgende newe effekte is aangemeld en die frekwensie is onbekend:
Hemolitiese anemie, eosinofilie en agranulositose is aangemeld. Hierdie reaksies is gewoonlik omkeerbaar met staking van terapie en daar word vermoed dat dit 'n hipersensitiwiteits fenomeen is.

Afwykings van die senuweestelsel:
Baie dikwels:
Hoofpyn.
Dikwels:
Stuiptrekkings. Stuiptrekkings mag voorkom saam met belemmerde nierfunksie of in diegene wat hoë dosisse ontvang.
Die volgende newe effekte is aangemeld en die frekwensie is onbekend:
Omkeerbare hiperaktiwiteit en duiseligheid.

Vaskulêre afwykings:
Die volgende newe effekte is aangemeld en die frekwensie is onbekend:
Hittegloede.

Algemene afwykings en afwykings by die plek van toediening:
Dikwels:
Moegheid.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Oordosering met amoksisillien is gewoonlik asimptomaties. Gastroïntestinale effekte soos naarheid, braking en diarree mag egter voorkom en die simptome van 'n water- en elektroliet wanbalans behoort simptomaties behandel te word.
Voldoende vloeistofinname en urienuitset moet onderhou word om die moontlikheid van kristalurie tot 'n minimum te beperk.
Amoksisillien kan met hemodialise uit die sirkulasie verwyder word. Die molekulêre massa, graad van proteïenbinding en farmakokinetiese profiel van klavulaansuur saam met inligting van 'n enkele pasiënt met ontoereikende nierfunksie wil daarop dui dat hierdie verbinding ook met hemodialise verwyder kan word.

IDENTIFIKASIE:
AURO-AMOXICLAV 125-31,25 mg/5 ml:
Wit tot byna wit granulêre poeier wat 'n wit tot byna wit oplossing met 'n aarbeismaak met hersamestelling met water vorm.
AURO-AMOXICLAV 250-62,5 mg/5 ml:
Wit tot byna wit granulêre poeier wat 'n wit tot byna wit oplossing met 'n aarbeismaak met hersamestelling met water vorm.

AANBIEDING:
AURO-AMOXICLAV 125-31,25 mg/5 ml:
1. HDPE bottel:
Die suspensie is verpak in 'n 150 ml swaardiens, deurskynende HDPE, ronde bottel met 'n 28 mm nek, verseël met 'n 28 mm poliepropelien induksie verseëlde skroefdop.
(100 ml suspensie na hersamestelling).
Pakgrootte: 100 ml suspensie.

2. Glas bottel:
Die suspensie is verpak in 'n 200 ml bruingekleurde, ronde glasbottel met 'n 28 mm nek, verseël met 'n wit 28 mm poliepropelien induksie verseëlde skroefdop, sonder weerstandbiedende pilfer sëel.
(100 ml suspensie na hersamestelling).
Pakgrootte: 100 ml suspensie.

AURO-AMOXICLAV 250-62,5 mg/5 ml:
1. HDPE bottel:
Die suspensie is verpak in 'n 150 ml swaardiens, deurskynende HDPE, ronde bottel met 'n 28 mm nek, verseël met 'n 28 mm poliepropelien induksie verseëlde skroefdop.
(100 ml suspensie na hersamestelling).
Pakgrootte: 100 ml suspensie.

2. Glas bottel:
Die suspensie is verpak in 'n 200 ml bruingekleurde, ronde glasbottel met n 28 mm nek, verseël met 'n wit 28 mm poliepropelien induksie verseëlde skroefdop, sonder weerstandbiedende pilfer sëel.
(100 ml suspensie na hersamestelling).
Pakgrootte: 100 ml suspensie.

BERGINGSINSTRUKSIES:
Bewaar by of benede 30 °C. Beskerm teen vogtigheid.

BERGING VIR HERSAAMGESTELDE SUSPENSIE
Hersaamgestelde suspensie behoort in 'n koelkas (2 – 8 °C) geberg te word en binne 7 dae opgebruik te word. Moenie bevries nie.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:
SUID-AFRIKA:
AURO-AMOXICLAV 125-31,25 mg/5 ml: 41/20.1.2/0963
AURO-AMOXICLAV 250-62,5 mg/5 ml: 41/20.1.2/0964

NAMIBIË:
AURO-AMOXICLAV 125-31,25 mg/ 5 ml: 10/20.1.2/0370
AURO-AMOXICLAV 250-62,5 mg/ 5 ml: 10/20.1.2/0371

NAAM EN ADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE:
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Namibië: **NS2**

AURO-AMOXICLAV 125-31,25 mg/5 ml (Poeier vir orale suspensie)
AURO-AMOXICLAV 250-62,5 mg/5 ml (Poeier vir orale suspensie)
Amoksisillien en klavulaansuur

Lees die hele brosjure sorgvuldig voordat u begin om hierdie medisyne te neem.
- Hou hierdie blaadjie. U mag dit moontlik weer wil lees.
- Indien u enige verdere vrae het, moet u asseblief u dokter of apteker raadpleeg.
- **AURO-AMOXICLAV** is vir u persoonlik voorgeskryf en u behoort nie u medisyne met ander mense deel nie. Dit mag hulle skade aandoen, ookal het hulle dieselfde simptome as u.

1. WAT AURO-AMOXICLAV BEVAT

Die aktiewe bestanddele is amoksisillien en klavulaansuur.

AURO-AMOXICLAV 125-31,25 mg/5 ml:

Elke 5 ml (na hersamestelling) bevat: amoksisillientrihidraat ekwivalent aan amoksisillien 125 mg en kaliumklavulanaat ekwivalent aan klavulaansuur 31,25 mg. Suikervry. Bevat versoeter: 5 mg aspartaam per 5 ml.

AURO-AMOXICLAV 250-62,5 mg/5 ml:

Elke 5 ml (na hersamestelling) bevat: amoksisillientrihidraat ekwivalent aan amoksisillien 250 mg en kaliumklavulanaat ekwivalent aan klavulaansuur 62,5 mg. Suikervry. Bevat versoeter: 10 mg aspartaam per 5 ml.

Die ander bestanddele in **AURO-AMOXICLAV** is aspartaam, hipromellose, kolloïdale anhidriese silika, silikondioksied, aarbei-guarana smaakmiddel, suksinielsuur, en xantaangom.

2. WAARVOOR AURO-AMOXICLAV GEBRUIK WORD

AURO-AMOXICLAV is 'n kombinasie van penisillien, amoksisillien en 'n beta-laktamaseïnhibeerder, klavulaansuur. Penisilliene en beta-laktamase-ïnhibeerders word gebruik om 'n wye verskeidenheid van infeksies wat deur bakterieë veroorsaak word, soos sinusitis, brongitis, longontsteking, tonsilitis, oorinfeksies, urienweginfeksies en infeksies van die vel te behandel. Amoksisillien werk deur die bakterieë te dood. Klavulaansuur word by die amoksisillien gevoeg om die amoksisillien teen sekere substanse (ensieme) wat die amoksisillien sal vernietig voordat dit die bakterieë kan dood, te beskerm.

3. VOORDAT U AURO-AMOXICLAV NEEM

Moenie AURO-AMOXICLAV neem:
- As u al ooit 'n allergiese reaksie teen amoksisillien, enige penisillienantibiotika of teen 'n kefalosporienantibiotika gehad het.
- As u voorheen geelsug (geel verkleuring van die vel en oë) en/of 'n lewersiekte gehad het wanneer die kombinasie van amoksisillien en klavulaansuur gebruik is.

Neem spesiale sorg met AURO-AMOXICLAV:
- 'n Ernstige vorm van diaree (pseudomembraneuse kolitis). Raadpleeg u dokter onmiddellik as maagpyn of –krampe, erge diaree of bloederige stoelgang voorkom.
- As u hoë dosisse gebruik, maak seker dat u voldoende vloeistof inneem.
- Kom alle afsprake met u dokter en laboratorium na. As u **AURO-AMOXICLAV** vir 'n lang periode gebruik, kan u dokter sekere toetse aanvra om u niere, lewer en bloed na te gaan.
- Indien u toetse ondergaan om suiker in u urien te monitor, moet u u dokter in kennis stel dat u **AURO-AMOXICLAV** gebruik. Dit is omdat **AURO-AMOXICLAV** die resultate van hierdie toetse mag beïnvloed.
- Die gebruik van **AURO-AMOXICLAV** kan tot 'n infeksie lei wat voorkom terwyl u vir 'n infeksie behandel word. As dit voorkom, behoort die gebruik van **AURO-AMOXICLAV** gestaak te word en die geskikte behandeling toegedien te word.

Voordat u met AURO-AMOXICLAV begin, moet u u dokter in kennis stel:

- As u aan 'n allergie of 'n geskiedenis van allergieë ly – Pasiënte met 'n geskiedenis van allergieë is meer geneig tot 'n allergie teen **AURO-AMOXICLAV** wat ernstig en moontlik fataal kan wees. Stel u dokter in kennis oor enige vorige allergiese reaksies teen penisilliene, kefalosporiene, ander medisyne, voedsel of ander middels.

Staak die gebruik van **AURO-AMOXICLAV** en kry noodhulp as u enige van hierdie tekens van 'n allergiese reaksie ondervind: Velbulte, moeite met asemhaling, swelling van u gesig, lippe, tong en keel.
- As u aan besmetlike mononukleose (klierkoors) of 'n seer keel ly.
- As u aan sifilis ly.
- As u aan limfatiese leukemie (bloedkanker) ly.
- As u aan 'n lewersiekte ly.
- As u aan 'n niersiekte ly.
- As u borsvoed.
- As u aan 'n bloedstollingsafwyking ly.

Die neem van AURO-AMOXICLAV met voedsel:

AURO-AMOXICLAV behoort aan die begin van 'n maaltyd geneem te word.

Swangerskap en borsvoeding:

- Die veiligheid van hierdie medisyne in swanger vroue is nie bevestig nie. Stel u dokter in kennis as u swanger of beplan om swanger te raak.
- **AURO-AMOXICLAV** kan na die borsmelk versprei en 'n gisinfeksie, diaree of allergiese reaksie in die sogende baba veroorsaak. Moenie hierdie medikasie gebruik sonder om u dokter in kennis te stel as u 'n baba borsvoed nie.

As u swanger is of u baba borsvoed, moet u asseblief u dokter, apteker of ander professionele gesondheidswerker om advies raadpleeg voordat u **AURO-AMOXICLAV** driink.

Die neem van ander medisyne saam met AURO-AMOXICLAV:

Sommige medisyne kan 'n interaksie met amoksisillien en klavulaansuur veroorsaak. Voordat u **AURO-AMOXICLAV** neem, moet u u dokter in kennis stel as u enige van die volgende medisyne gebruik:

- Orale voorbehoedmiddels – U orale voorbehoedmiddel mag moontlik nie behoorlik werk nie. U sal moontlik bykomende voorbehoedmiddels, soos bv. 'n kondoom moet gebruik. As u advies nodig het, moet u u dokter of apteker raadpleeg.
- Allopurinol, 'n middel wat vir jig gebruik word.
- Enige medisyne wat gebruik word om bloedklonte te voorkom, soos warfarien.
- Tetrasiklienantibiotika.
- Ander antibiotika.

As u enige van die hierdie medisyne gebruik, is u moontlik nie in staat om **AURO-AMOXICLAV** te gebruik nie, die dosis mag moontlik aangepas word of u dokter sal u noukeurig vir newe effekte monitor.

Stel altyd u professionele gesondheidswerker in kennis as u enige ander medisyne gebruik. (Dit sluit komplementêre en tradisionele medisyne in).

4. HOE OM AURO-AMOXICLAV TE NEEM

Neem altyd **AURO-AMOXICLAV** presies soos deur u dokter voorgeskryf. Bevestig met u dokter of apteker as u onseker is. As u van mening is dat die effek van **AURO-AMOXICLAV** te sterk of te swak is, moet u u dokter of apteker raadpleeg.

- **AURO-AMOXICLAV** behoort aan die begin van 'n maaltyd geneem te word om 'n omgekrapte maag te voorkom.
- Skud die vloeistof goed voor elke gebruik om die medikasie eweredig te meng.
- Om te verseker dat u die korrekte dosis neem, moet u die vloeistof met die gemerkte maatlepel meet.
- Neem hierdie medikasie vir die volle tydperk, soos deur u dokter voorgeskryf.
- Die normale dosis van **AURO-AMOXICLAV** in kinders is 25 – 50 mg/kg/dag, geneem in verdeelde dosisse elke 8 ure (drie keer per dag).
- Die dosis vir kinders word op liggaamsmassa gebaseer en moet deur u dokter bereken word.
- Stel u dokter in kennis as u aan 'n niersiekte ly – die dosis behoort moontlik aangepas te word.

As u te veel AURO-AMOXICLAV geneem het:

Simptome van oordosering mag mislikheid of naarheid, braking, diaree of kristalle in die urien, wat as melkerige urien vertoon, of probleme met urinering insluit.

In die geval van oordosering, raadpleeg u dokter of apteker. As hulle nie beskikbaar is nie, kontak u naaste hospitaal of gifbeheersentrum.

As u vergeet het om AURO-AMOXICLAV te neem:

Neem die oorgeslaande dosis so gou as wat u daarvan onthou. Indien dit egter byna tyd vir die volgende dosis is, slaan dan die dosis oor en gaan voort met die normale dosisskedulering. Moenie die dosis verdubbel om vir die oorgeslaande dosis op te maak nie.

5. MOONTLIKE NEWE EFFEKTE

AURO-AMOXICLAV kan newe effekte hê.

Kry nood mediese hulp as u enige van hierdie tekens van 'n allergiese reaksie toon:

- Velbulte.
- Moeite met asemhaling.
- Swelling van u gesig, lippe, tong of keel.

Stel u dokter onmiddellik in kennis as u enige van hierdie ernstige newe effekte ondervind:

- Hoë temperatuur (koors), kouekoors, seer keel of ander tekens van 'n infeksie, of as u maklik kneusing opdoen. Dit mag 'n teken van 'n probleem met u bloedselle beteken.
- Ongewone bloeding – u bloed mag langer as gewoonlik neem om te stol. U mag dit waarneem wanneer u uself raak sny of wanneer u neus bloei.
- Bleek vel, oormatige moegheid.
- 'n Vertraagde allergiese reaksie wat soms die volgende insluit: uitslag, koors, gewrigspyn en swelling van die limfkliere.
- 'n Velreaksie wat as “erythema multiforme” bekend staan, waar u jeukerige rooi/pers vlekke op die vel ontwikkel. U mag koorsig voel en baie moeg wees.
- Ander ernstige velreaksies kan die volgende insluit: veranderinge in velkleur, knoppe onder die vel, blaasvorming, puisies, velloslating, rooiheid, pyn, jeuk, afskilfering. Dit kan met koors, hoofpyn en liggaamspyn gepaard gaan.
- Uitslag of klein speldepunt rooi kolletjies onder die veloppervlak of kneusing van die vel. Dit is weens inflammasie van die bloedvatwande as gevolg van 'n allergiese reaksie. Dit kan met gewrigspyn en nierprobleme gepaard gaan.
- Stuipaanvalle gesien in pasiënte op hoë dosisse of met nierprobleme.
- Naarheid, maagpyn, lae koors, verlies aan eetlus, geel verkleuring van die vel of oë, donker urien, kleigekleurde stoelgang.
- Inflammasie van die dikderm (kolon) met erge diaree wat waterig of bloederig is, pyn en koors.
- Minder urinering as gewoonlik of glad nie.

Ander moontlike newe effekte is:

- Matige veluitslag
- Hiperaktiwiteit
- Duiseligheid
- Hoofpyn
- Naarheid
- Braking
- Diaree
- Maag-/buikpyn
- Indigestie
- Smaakafwyking
- Tande vertoon gevlek, keer gewoonlik terug na normaal met borsel
- Seer mond of tong
- Swart of “harige” tong
- Sproei (wit vlekke in die mond)
- Vaginale jeuk of uitskeiding newe-effekte
- Warm gloede
- Kristalle in die urien wat melkerig mag lyk, of moeite of ongemak met urienlating. Maak seker dat u voldoende vloeistof inneem om die voorkoms van hierdie simptome te verminder

Stel u dokter so gou as moontlik in kennis as enige van die bogenoemde erg of kwellend is, of as hulle nie verdwyn nie of as u enige besorgdheid het terwyl u **AURO-AMOXICLAV** neem.

Nie al die newe effekte wat vir hierdie medisyne aangemeld is, word in hierdie brosjure ingesluit nie. As u algemene gesondheid agteruitgaan of as u enige ongewone effekte ondervind terwyl u **AURO-AMOXICLAV** neem, moet u asseblief u dokter, apteker of ander professionele gesondheidswerker om advies raadpleeg.

6. OPBERGING EN WEGDOEN VAN AURO-AMOXICLAV

Bewaar alle medisyne buite die bereik van kinders.

Vir droë poeier:

Bewaar by of benede 30 °C (kamertemperatuur) en weg van vogtigheid (nie in die badkamer nie).

Vir hersaamgestelde suspensie:

Na hersamestelling behoort die suspensie (vloeibare medikasie) in 'n yskas gehou te word. Doen alle ongebruikte medikasie na 7 dae weg. Moenie bevries nie. Skud die bottel deeglik voor gebruik.

Neem alle ongebruikte medisyne na u apteker terug.

Moenie enige ongebruikte medisyne in die drein of riolering (bv. toilette) weggooi nie.

7. AANBIEDING VAN AURO-AMOXICLAV

AURO-AMOXICLAV 125-31,25 mg/5 ml:

Een 150 ml swaardiens HDPE, deurskynende ronde bottel met 'n skroefdop, verpak in 'n gedrukte karton houer met 'n voubiljet.
(100 ml suspensie na hersamestelling).
Een 200 ml bruingekleurde, ronde glasbottel met 'n skroefdop, verpak in 'n gedrukte karton houer met 'n voubiljet.
(100 ml suspensie na hersamestelling).

AURO-AMOXICLAV 250-62,5 mg/5 ml:

Een 150 ml swaardiens HDPE, deurskynende ronde bottel met 'n skroefdop, verpak in 'n gedrukte karton houer met 'n voubiljet.
(100 ml suspensie na hersamestelling).
Een 200 ml bruingekleurde, ronde glasbottel met 'n skroefdop, verpak in 'n gedrukte karton houer met 'n voubiljet.
(100 ml suspensie na hersamestelling).

8. IDENTIFIKASIE VAN AURO-AMOXICLAV

AURO-AMOXICLAV 125-31,25 mg/5 ml:
Wit tot byna-wit poeier wat 'n wit tot byna-wit suspensie met 'n aarbeigeur na hersamestelling met water vorm.

AURO-AMOXICLAV 250-62,5 mg/5 ml:
Wit tot byna-wit poeier wat 'n wit tot byna-wit suspensie met 'n aarbeigeur na hersamestelling met water vorm.

9. REGISTRASIENOMMER / VERWYSINGSNOMMER

SUID-AFRIKA:
AURO-AMOXICLAV 125-31,25 mg/5 ml: 41/20.1.2/0963
AURO-AMOXICLAV 250-62,5 mg/5 ml: 41/20.1.2/0964

NAMIBIË:
AURO-AMOXICLAV 125-31,25 mg/ 5 ml: 10/20.1.2/0370
AURO-AMOXICLAV 250-62,5 mg/ 5 ml: 10/20.1.2/0371

10. NAAM EN ADRES VAN DIE REGISTRASIEHOUER

Aurogen South Africa (Edms) Bpk
Woodhill Kantoorpark, Gebou Nr. 1, Eerste vloer
Phillip Engelbrechtlaan 53
Meyersdal Uitbr. 12,
1448
Johannesburg
Suid Afrika

11. DATUM VAN PUBLIKASIE

Datum van registrasie:
17 April 2009

Datum van hersiening:
01 Augustus 2021

SCHEDULING STATUS:

South Africa: S4
Namibia: NS2

PROPRIETARY NAME (and dosage form):

AURO-AMOXICLAV 125-31,25 mg/5 ml (Powder for oral suspension)
AURO-AMOXICLAV 250-62,5 mg/5 ml (Powder for oral suspension)

COMPOSITION:
AURO-AMOXICLAV 125-31,25 mg/5 ml:
Each 5 ml (after reconstitution) contains: amoxicillin trihydrate equivalent to amoxicillin 125 mg and potassium clavulanate equivalent to clavulanic acid 31,25 mg. Sugar free. Contains sweetener: 5 mg aspartame per 5 ml.
AURO-AMOXICLAV 250-62,5 mg/5 ml:
Each 5 ml (after reconstitution) contains: amoxicillin trihydrate equivalent to amoxicillin 250 mg and potassium clavulanate equivalent to clavulanic acid 62,5 mg. Sugar free. Contains sweetener: 10 mg aspartame per 5 ml.
List of exipients:
Aspartame, hypromellose, silica colloid alanhydrous, silicon dioxide, strawberry guarana flavour, succinic acid, syloid and xanthum gum.

PHARMACOLOGICAL CLASSIFICATION:
A 20.1.2 Penicillins

PHARMACOLOGICAL CLASSIFICATION:
AURO-AMOXICLAV is a combination of amoxicillin and clavulanic acid.
Amoxicillin is a semisynthetic beta-lactamase-susceptible penicillin, which has *in vitro* bactericidal activity against a broad spectrum of non beta-lactamase-producing Gram positive and Gram negative organisms. The spectrum of activity does not include those organisms that produce beta-lactamases, namely resistant staphylococci, and all strains of *Pseudomonas, Klebsiella* and *Enterobacter.*
Clavulanic acid has been shown *in vitro* to be an irreversible inhibitor of beta-lactamases produced by: *Staphylococcus aureus, Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Haemophilus influenzae, Neisseria gonorrhoea* and *Bacteroides fragilis.* Clavulanic acid does not inactivate the chromosomally mediated (Sykes Type 1 Cephalosporinase) beta-lactamases produced by *Acinetobacter* species, *Citrobacter* species, *Enterobacter,* Indole positive *Proteus, Providencia* species and *Serratia marcescens. In vitro* the formulation showed synergism against amoxicillin-resistant organisms, with no evidence of antagonism and the activity was not reduced in the presence of serum.
(In vitro activity does not necessarily imply *in vivo* efficacy.)

Pharmacokinetics:
Absorption:
Amoxicillin is stable in the presence of acidic gastric secretions. Peak blood levels are achieved 1 - 2 hours after administration. There is a linear dose response in peak serum levels.
The pharmacokinetics of amoxicillin and clavulanic acid are closely allied and neither is adversely affected by the presence of food in the stomach.
Distribution:
Approximately 18 % of the total plasma amoxicillin content is protein bound. Amoxicillin diffuses readily into most body tissues with the exception of the brain and spinal fluid. Inflammation generally increases the permeability of the meninges to penicillins and this may apply to amoxicillin.
Excretion:
The elimination half-life of amoxicillin is approximately 1 hour. Small amounts of amoxicillin are also excreted in the faeces and bile.

INDICATIONS:
AURO-AMOXICLAV formulations are indicated for the treatment of infections caused by amoxicillin resistant organisms producing beta-lactamases sensitive to clavulanic acid:
Upper respiratory tract infections, such as sinusitis, recurrent otitis media and tonsillitis.
Lower respiratory tract infections, such as bronchitis and bronchopneumonia.
Genito-urinary tract infections, such as cystitis, urethritis, pyelonephritis.
Skin and soft tissue infections.
AURO-AMOXICLAV 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.

CONTRA-INDICATIONS:
Hypersensitivity to penicillins or to cephalosporins. Cross-sensitivity between penicillins and cephalosporins is well documented.
AURO-AMOXICLAV is contra-indicated in patients with a previous history of amoxicillin/clavulanic acid-associated jaundice/hepatic dysfunction.

WARNINGS AND SPECIAL PRECAUTIONS:
Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin therapy. Before initiating therapy with **AURO-AMOXICLAV**, 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 cephalosporins.
If an allergic reaction occurs, **AURO-AMOXICLAV** 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.
AURO-AMOXICLAV should be avoided if infectious mononucleosis is suspected since the occurrence of a morbilliform rash has been associated with this condition following the use of amoxicillin.
Prolonged use may result in overgrowth of non-susceptible organisms. Pseudomembranous enterocolitis has been reported.
Prolongation of prothrombin time has been reported rarely in patients receiving **AURO-AMOXICLAV**.
Appropriate monitoring should be undertaken when anticoagulants are prescribed concurrently.
Periodic assessment of organ function, including renal, hepatic and haematopoietic functions, is advisable during prolonged therapy.

Transient hepatitis and cholestatic jaundice has been reported. **AURO-AMOXICLAV** should be used with caution in patients with evidence of hepatic dysfunction.

Caution is needed when administering **AURO-AMOXICLAV** 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.
Since **AURO-AMOXICLAV** contains amoxicillin, an aminopenicillin, it is not the treatment of choice in patients presenting with sore throat or pharyngitis because of the possibility that the underlying cause is infectious mononucleosis, in the presence of which there is a high incidence of rash if amoxicillin is used. **AURO-AMOXICLAV** should be given with caution to patients with lymphatic leukemia since they are especially susceptible to amoxicillin induced skin rashes.
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.

Impaired hepatic function:
Changes in liver function tests have been observed in some patients receiving **AURO-AMOXICLAV**. It should be used with care in patients with evidence of severe hepatic dysfunction.

Impaired renal function:
In patients with moderate or severe renal impairment **AURO-AMOXICLAV** dosage should be adjusted (See "**DOSAGE AND DIRECTIONS FOR USE**").

Use in lactation:
Amoxicillin is excreted in the milk; there is no data on the excretion of clavulanic acid in human milk. Therefore, caution should be exercised when **AURO-AMOXICLAV** is administered to a nursing woman.
The use of **AURO-AMOXICLAV** may lead to the selection of resistant strains of organisms and sensitivity testing should, therefore, be carried out whenever possible to demonstrate the appropriateness of therapy.

INTERACTIONS:
AURO-AMOXICLAV may reduce the efficacy of oral contraceptives and patients should be warned accordingly.
The concomitant administration of allopurinol and **AURO-AMOXICLAV** substantially increases the incidence of skin rashes in patients receiving both agents as compared to patients receiving ampicillin alone. It is not known whether this potentiation of ampicillin rashes is due to allopurinol or the hyperuricaemia present in these patients.
Tetracyclines and other bacteriostatic drugs may interfere with the bactericidal effects of amoxicillin.

Interaction with laboratory tests:
It is recommended that when testing for the presence of glucose in urine during **AURO-AMOXICLAV** treatment, enzymatic glucose oxidase methods should be used. Due to the high urinary concentrations of amoxicillin, false positive readings are common with chemical methods.

PREGNANCY AND LACTATION:
Use in Pregnancy:
The safety of **AURO-AMOXICLAV** in pregnancy has not been established.

Use in Lactation:
Amoxicillin is distributed into breast milk. Although significant problems in humans have not been documented, the use of **AURO-AMOXICLAV** by breastfeeding mothers may lead to sensitisation, diarrhoea, candidiasis and skin rash in the infant.

DOSAGE AND DIRECTIONS FOR USE:
Directions for reconstitution:
AURO-AMOXICLAV 125-31,25 mg/5 ml:
For reconstitution to 100 ml, add 92 ml water, invert the bottle and shake well until all the powder is dispersed.
AURO-AMOXICLAV 250-62,5 mg/5 ml:
For reconstitution to 100 ml, add 90 ml water, invert the bottle and shake well until all the powder is dispersed.
AURO-AMOXICLAV suspension may be taken immediately before a meal.
Dosage:
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.
Children:
The dose of **AURO-AMOXICLAV** in children is 25-50 mg/kg/day of the 4 parts amoxicillin, 1 part clavulanic acid preparations (which corresponds to a daily dosage of the equivalent of 20-40 mg/kg of amoxicillin and 5-10 mg/kg of clavulanic acid) to be taken in divided doses every eight hours, at the start of a meal.
Dosage Guide:

Amoxicillin-Sensitive Organisms

Product	Upper Respiratory Tract Infections	Lower Respiratory Tract Infections	Urinary Tract Infections	Skin & Soft Tissue Infections
AURO-AMOXICLAV 125-31,25 mg/5 ml (9-18 kg)	5-10 ml * 8 hourly	5-10 ml * 8 hourly	5-10 ml * 8 hourly	5-10 ml * 8 hourly
AURO-AMOXICLAV 250-62,5 mg/5 ml (18-37 kg)	5 ml * 8 hourly	5 ml * 8 hourly	5 ml * 8 hourly	5 ml * 8 hourly

Amoxicillin-Resistant Organisms

Product	Upper Respiratory Tract Infections (Otitis media)	Lower Respiratory Tract Infections (Bronchitis)	Urinary Tract Infections	Skin & Soft Tissue Infections
AURO-AMOXICLAV 125-31,25 mg/5 ml (9-18 kg)	5-10 ml ^ 8 hourly	5-10 ml * 8 hourly	5-10 ml * 8 hourly	5-10 ml * 8 hourly
AURO-AMOXICLAV 250-62,5 mg/5 ml (18-37 kg)	5-10 ml ^ 8 hourly	5-10 ml * 8 hourly	5-10 ml * 8 hourly	5-10 ml * 8 hourly

* To correspond to a dosage of 25-50 mg/kg/day.
^ To correspond to a dosage of 50 mg/kg/day.

SIDE EFFECTS:
The incidence and severity of adverse effects, particularly nausea and diarrhoea, increases with the higher recommended dose and can be minimised by administering **AURO-AMOXICLAV** at the start of a meal. In addition, as these symptoms are especially related to the potassium clavulanate component, where these gastrointestinal symptoms occur and a higher concentration of amoxicillin is required, consideration should be given to administering the additional amoxicillin separately.

The following adverse reactions have been reported and may occur with **AURO-AMOXICLAV:**
Immune system disorders:
Less frequent:
Skin rashes, pruritus and urticaria, serum sickness-like syndrome, erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported. Whenever such reactions occur, **AURO-AMOXICLAV** should be discontinued. Serious and occasional fatal hypersensitivity (anaphylactic) reactions and angioneurotic oedema can occur with oral penicillin (see "**WARNINGS AND SPECIAL PRECAUTIONS**").
The following side effects have been reported and frequencies are unknown:
Hypersensitivity, vasculitis and bullous exfoliative dermatitis. Whenever such reactions occur, **AURO-AMOXICLAV** should be discontinued.
Interstitial nephritis can occur.

Gastrointestinal disorders:
Frequent:
Nausea, vomiting, diarrhoea.
Less frequent:
Glossitis.
The following side effects have been reported and frequencies are unknown:
Indigestion, abdominal pain, gastritis, stomatitis, black 'hairy' tongue, enterocolitis, mucocutaneous candidiasis and antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis) and abnormal taste. Superficial tooth discolouration has been reported especially with the suspension formulations. It can usually be removed by brushing.
If gastrointestinal reactions are evident, they may be reduced by taking **AURO-AMOXICLAV** at the start of a meal.

Hepato-biliary disorders:
Less frequent:
Hepatitis and cholestatic jaundice have been reported. The events may be severe, and occur predominantly in adults or elderly patients. Signs and symptoms usually occur during or shortly after treatment, but in some cases may not become apparent until several weeks after treatment has ceased. The hepatic effects are usually reversible. However, in extremely rare circumstances, death has been reported. These have almost always been cases associated with serious underlying disease or concomitant medication. A moderate rise in aspartate transaminase (AST) and/or alanine transaminase (ALT) has been noted in patients treated with **AURO-AMOXICLAV**.

Renal and urinary disorders:
The following side effects have been reported and frequencies are unknown:
Crystalluria.

Reproductive system and breast disorders:
The following side effects have been reported and frequencies are unknown:
Vaginitis.

Blood and the lymphatic system disorders:
Less frequent:
Reversible thrombocytopenia, thrombocytopenic purpura and reversible leucopenia have been reported. These reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena. A slight thrombocytosis was noted in less than 1 % of the patients treated with **AURO-AMOXICLAV**. Prolongation of bleeding time and prothrombin time have also been reported less frequently.
Appropriate monitoring should be undertaken when anticoagulants are prescribed concomitantly.
The following side effects have been reported and frequencies are unknown:
Haemolytic anaemia, eosinophilia and agranulocytosis have been reported. These reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena.

Nervous system disorders:
Frequent:
Headache.
Less frequent:
Convulsions may occur with impaired renal function or in those receiving high doses.
The following side effects have been reported and frequencies are unknown:
Reversible hyperactivity and dizziness.

Vascular disorders:
The following side effects have been reported and frequencies are unknown:
Hot flushes.

General disorders and administrative site conditions:
Less frequent:
Tiredness.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Overdosage with amoxicillin is usually asymptomatic. However, gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and symptoms of water and electrolyte imbalance should be treated symptomatically.
Adequate fluid intake and urinary output must be maintained to minimise the possibility of crystalluria.
Amoxicillin may be removed from the circulation by haemodialysis. The molecular weight, degree of protein binding and pharmacokinetic profile of clavulanic acid together with information from a single patient with renal insufficiency all suggest that this compound may also be removed by haemodialysis.

IDENTIFICATION:
AURO-AMOXICLAV 125-31,25 mg/5 ml:
White to off white granular powder forming a white to off white suspension with a strawberry flavour on constitution with water.
AURO-AMOXICLAV 250-62,5 mg/5 ml:
White to off white granular powder forming a white to off white suspension with a strawberry flavour on constitution with water.

PRESENTATION:
AURO-AMOXICLAV 125-31,25 mg/5 ml:
1. HDPE bottle:
The suspension is packed in a heavy weight 150 ml HDPE translucent, round bottle with a 28 mm neck closed with a 28 mm polypropylene screw cap with an induction sealing wad.
(100 ml of suspension after reconstitution).
Pack size: 100 ml suspension.

2. Glass bottle:
The suspension is packed in a 200 ml amber coloured, round glass bottle with a 28 mm neck closed with a 28 mm white polypropylene screw cap, without a pilfer proof skirt, but with an induction sealing wad.
(100 ml of suspension after reconstitution).
Pack size: 100 ml suspension.

AURO-AMOXICLAV 250-62,5 mg/5 ml:
1. HDPE bottle:
The suspension is packed in a heavy weight 150 ml HDPE translucent, round bottle with a 28 mm neck closed with a 28 mm polypropylene screw cap with an induction sealing wad.
(100 ml of suspension after reconstitution).
Pack size: 100 ml suspension.

2. Glass bottle:
The suspension is packed in a 200 ml amber coloured, round glass bottle with a 28 mm neck closed with a 28 mm white polypropylene screw cap, without a pilfer proof skirt, but with an induction sealing wad.
(100 ml of suspension after reconstitution).
Pack size: 100 ml suspension.

STORAGE INSTRUCTIONS:
Store at or below 30 °C. Protect from moisture.

STORAGE OF RECONSTITUTED SUSPENSION
Reconstituted suspension should be kept in a refrigerator (2-8 °C) and used within 7 days. Do not freeze.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
SOUTH AFRICA:
AURO-AMOXICLAV 125-31,25 mg/5 ml: 41/20.1.2/0963
AURO-AMOXICLAV 250-62,5 mg/5 ml: 41/20.1.2/0964

NAMIBIA:
AURO-AMOXICLAV 125-31,25 mg/5 ml: 10/20.1.2/0370
AURO-AMOXICLAV 250-62,5 mg/ 5 ml: 10/20.1.2/0371

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Aurogen South Africa (Pty) Ltd
Woodhill Office Park
Building No. 1, First floor
53 Phillip Engelbrecht Avenue
Meyersdal
Ext. 12
1448
Johannesburg
South Africa

DATE OF PUBLICATION OF THE PACKAGE INSERT
Date of registration:
17 April 2009
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South Africa: S4
Namibia: NS2

AURO-AMOXICLAV 125-31,25 mg/5 ml (Powder for oral suspension)
AURO-AMOXICLAV 250-62,5 mg/5 ml (Powder for oral suspension)
Amoxicillin and clavulanic acid

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **AURO-AMOXICLAV** 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.

1. WHAT AURO-AMOXICLAV CONTAINS

The active substances are amoxicillin and clavulanic acid.

AURO-AMOXICLAV 125-31,25 mg/5 ml:
Each 5 ml (after reconstitution) contains: amoxicillin trihydrate, equivalent to amoxicillin 125 mg and potassium clavulanate equivalent to clavulanic acid 31,25 mg. Sugar free. Contains sweetener: 5 mg aspartame per 5 ml.

AURO-AMOXICLAV 250-62,5 mg/5 ml:
Each 5 ml (after reconstitution) contains: amoxicillin trihydrate, equivalent to amoxicillin 250 mg and potassium clavulanate equivalent to clavulanic acid 62,5 mg. Sugar free. Contains sweetener: 10 mg aspartame per 5 ml.

The other ingredients contained in **AURO-AMOXICLAV** are aspartame, hypromellose, silica colloidal anhydrous, silicon dioxide, strawberry guarana flavour, succinic acid, and xanthum gum.

2. WHAT AURO-AMOXICLAV IS USED FOR

AURO-AMOXICLAV is a combination of a penicillin, amoxicillin and a beta-lactamase inhibitor, clavulanic acid. Penicillins and beta-lactamase inhibitors are used to treat many different infections caused by bacteria, such as sinusitis, bronchitis, pneumonia, tonsilitis, ear infections, urinary tract infections and infections of the skin. Amoxicillin works by killing the bacteria. Clavulanic acid is added to the amoxicillin to protect the amoxicillin from certain substances (enzymes) that will destroy the amoxicillin before it can kill the bacteria.

3. BEFORE YOU TAKE AURO-AMOXICLAV

Do not take AURO-AMOXICLAV:
- If you have ever had an allergic reaction to amoxicillin, to any other penicillin antibiotic, or to a cephalosporin antibiotic.
- If you have previously had jaundice (yellow pigmentation of skin and eyes) and/or liver disease when using the combination of amoxicillin and clavulanic acid.

Take special care with AURO-AMOXICLAV:
- A serious form of diarrhoea (pseudomembranous colitis) may occur. Contact your doctor right away if stomach pain or cramps, severe diarrhoea, or bloody stools occur.
- If you are taking high doses, make sure you drink plenty of fluids.
- Keep all appointments with your doctor and laboratory. If you are taking **AURO-AMOXICLAV** for a long period of time, your doctor may order certain tests to check your kidneys, liver and blood.
- If you are having tests on or checking your urine for sugar, let the doctor know that you are on **AURO-AMOXICLAV**. This is because **AURO-AMOXICLAV** can affect the results of these tests.
- Use of **AURO-AMOXICLAV** may result in an infection that occurs while you are being treated for an infection. If this occurs, **AURO-AMOXICLAV** should be stopped and suitable treatment given.

Before using AURO-AMOXICLAV, tell your doctor if you:
- have allergies or a history of allergies – Patients with a history of allergies are more likely to have a allergic reaction to **AURO-AMOXICLAV** which can be serious and possibly fatal. Tell your doctor about any previous allergic reactions to penicillins, cephalosporins, other medicines, food, or other substances.

Stop taking **AURO-AMOXICLAV** and get emergency help if you have any of these signs of an allergic reaction: hives; difficulty breathing; swelling of your face, lips, tongue or throat.
- have infectious mononucleosis (glandular fever) or a sore throat.
- have syphilis.
- have lymphatic leukemia (cancer of the blood).
- have liver disease.
- have kidney disease.
- are breastfeeding.
- have a blood clotting disorder.

Taking AURO-AMOXICLAV with food:
AURO-AMOXICLAV should be taken immediately before a meal.

Pregnancy and Breastfeeding:
- The safety of this medicine in pregnant women has not been confirmed - Tell your doctor if you are pregnant or plan to become pregnant.
- **AURO-AMOXICLAV** can pass into breast milk and may cause a yeast infection, diarrhoea, or allergic reaction in a nursing baby. Do not use this medication without telling your doctor if you are breastfeedijng a baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking **AURO-AMOXICLAV**.

Taking other medicines with AURO-AMOXICLAV:
Some medicines may interact with amoxicillin and clavulanic acid. Before taking **AURO-AMOXICLAV**, tell your doctor if you are using any of the following medicines:
- oral contraceptives – Your oral contraceptive may not work properly. You will need to use extra contraceptive precautions, such as using a condom. If you need any advice, talk to your doctor or pharmacist.
- allopurinol, a medicine used for gout.
- any medicine to stop blood clots, such as warfarin.
- tetracycline antibiotics.
- another antibiotic.

If you are using any of these medicines, you may not be able to take **AURO-AMOXICLAV**, or you may need dosage adjustments or your doctor may need to monitor you carefully for side effects.

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

4. HOW TO TAKE AURO-AMOXICLAV

Always take **AURO-AMOXICLAV** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **AURO-AMOXICLAV** is too strong or too weak, talk to your doctor or pharmacist.

- **AURO-AMOXICLAV** should be taken at the start of a meal, to help prevent stomach upset.
- Shake the liquid well before each use to mix the medication evenly.
- To be sure you get the correct dose, measure the liquid with a marked measuring spoon.
- Take this medication for the entire length of time prescribed by your doctor.
- The usual dose of **AURO-AMOXICLAV** in children is 25 - 50 mg/kg/day, taken in divided doses every 8 hours (three times a day).
- The dose for children is based on body weight and must be determined by your doctor.
- Tell your doctor if you suffer from kidney disease – your dosage may need to be adjusted.

If you take more AURO-AMOXICLAV than you should:
Overdose symptoms may include queasiness or feeling that one is about to vomit, vomiting, diarrhoea, or crystals in the urine, which may be seen as cloudy urine, or problems passing urine.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take AURO-AMOXICLAV:
Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

5. POSSIBLE SIDE EFFECTS

AURO-AMOXICLAV can have side effects.
Get emergency medical help at once if you have any of these signs of an allergic reaction:
- hives
- difficulty breathing
- swelling of your face, lips, tongue, or throat.

Call your doctor at once if you have any of these serious side effects:
- high temperature (fever), chills, a sore throat or other signs of an infection, or if you bruise easily. These may be signs of a problem with your blood cells.
- Unusual bleeding - your blood may take longer to clot than it normally would. You may notice this if you cut yourself or have a nosebleed.
- pale skin, excessive tiredness.
- a delayed allergic reaction, some signs include: rashes, fever, joint pains and enlargement of the lymph nodes.
- a skin reaction known as “erythema multiforme”, where you may develop: itchy reddish purple patches on the skin. You may have a fever and be very tired.
- other severe skin reactions can include: changes in skin colour, bumps under the skin, blistering, pustules, peeling, redness, pain, itching, scaling. These may be associated with fever, headaches, and body aches.
- rash or pinpoint flat red round spots under the skin surface or bruising of the skin. This is due to inflammation of blood vessel walls due to an allergic reaction. It can be associated with joint pain and kidney problems.
- convulsions (seizures), seen in patients on high doses or with kidney problems.
- nausea, stomach pain, low fever, loss of appetite, yellowing of the skin or eyes, dark urine, or clay-coloured stools.
- inflammation of the large bowel (colon) with severe diarrhoea that is watery or bloody, pain and fever.
- urinating less than usual or not at all.

Other possible side effects are:
- mild skin rash
- hyperactivity
- dizziness
- headache
- feeling sick (nausea)
- being sick (vomiting)
- diarrhoea
- stomach/abdominal pain
- indigestion
- taste disturbances
- teeth may appear stained, usually returning to normal with brushing
- sore mouth or tongue
- black, or “hairy” tongue
- thrush (white patches inside your mouth)
- vaginal itching or discharge
- hot flushes
- crystals in the urine, which may be seen as a cloudy urine, or difficulty or discomfort in passing urine. Make sure you drink plenty of fluids to reduce the chance of these symptoms.

Tell your doctor if any of the above side effects are severe, bothersome, do not go away or about any concerns you have while taking **AURO-AMOXICLAV**.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **AURO-AMOXICLAV**, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF AURO-AMOXICLAV

Store all medicines out of the reach of children.

For dry powder:
Store at or below 30 °C (room temperature) and away from moisture (not in the bathroom).
For reconstituted suspension:
Once reconstituted, the suspension (liquid medication) should be kept in a refrigerator. Throw away any unused medication after 7 days. Do not freeze. Shake the bottle well before use.

Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF AURO-AMOXICLAV

AURO-AMOXICLAV 125-31,25 mg/5 ml:
One 150 ml heavy weight HDPE translucent, round bottle closed with a screw cap packed in a printed carton with a package insert.
(100 ml of suspension after reconstitution)
One 200 ml amber coloured, round glass bottle closed with a screw cap packed in a printed carton with a package insert.
(100 ml of solution after reconstitution).

AURO-AMOXICLAV 250-62.5 mg/5 ml:
One 150 ml heavy weight HDPE translucent, white opaque round bottle closed with a screw cap packed in a printed carton with a package insert.
(100 ml of suspension after reconstitution).
One 200 ml amber coloured, round glass bottle closed with a screw cap packed in a printed carton with a package insert.
(100 ml of solution after reconstitution).

8. IDENTIFICATION OF AURO-AMOXICLAV

AURO-AMOXICLAV 125-31,25 mg/5 ml:
White to off white granular powder forming a white to off white suspension with a strawberry flavour on constitution with water.
AURO-AMOXICLAV 250-62,5 mg/5 ml:
White to off white granular powder forming a white to off white suspension with a strawberry flavour on constitution with water.

9. REGISTRATION NUMBERS/REFERENCE NUMBERS

SOUTH AFRICA:
AURO-AMOXICLAV 125-31,25 mg/5 ml: 41/20.1.2/0963
AURO-AMOXICLAV 250-62,5 mg/5 ml: 41/20.1.2/0964

NAMIBIA:
AURO-AMOXICLAV 125-31,25 mg/5 ml: 10/20.1.2/0370
AURO-AMOXICLAV 250-62,5 mg/ 5 ml: 10/20.1.2/0371

10. NAME AND ADDRESS OF REGISTRATION HOLDER
Aurogen South Africa (Pty) Ltd
Woodhill Office Park, Building 1, First floor
53 Phillip Engelbrecht Avenue,
Meyersdal, Ext. 12,
1448,
Johannesburg,
South Africa

11. DATE OF PUBLICATION

Date of registration:
17 April 2009
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01 August 2021

AUROBINDO Packaging Development

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				No. of Colours : 1
	Customer / Country	Version No.	Reason of Issue	■ Black
	South_Africa	01	New	
Team Leader: Kiran Kumar	Dimensions	Font Type	Font Size	
Initiator: Bhogeswara Rao	A/s: 350 x 560 mm Booklet Size: 35 x 60 mm	Helvetica	6 pt	
Design Agency: vakils PREMEDIA	Pharmacode: 29121			

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1. 08-FEB-2022 (Adi) - FR
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Sign / Date