SKEDULERINGSTATUS

SUID-AFRIKA: **S4**

NAMIBIË: **NS2**

EIENDOMSNAAM (en doseervorm):
AURO AMOXICLAV 375 mg (tablet)
AURO AMOXICLAV 625 mg (tablet)
AURO AMOXICLAV 1000 mg (tablet)

SAMESTELLING:
AURO AMOXICLAV 375 mg:
Elke filmbedekte tablet bevat amoksisillientrihidraat ekwivalent aan 250 mg amoksisillien en kaliumklavulanaat ekwivalent aan 125 mg klavuulaansuur. Suikervry.

AURO AMOXICLAV 625 mg:
Elke filmbedekte tablet bevat amoksisillientrihidraat ekwivalent aan 500 mg amoksisillien en kaliumklavulanaat ekwivalent aan 125 mg klavuulaansuur. Suikervry.

AURO AMOXICLAV 1000 mg:
Elke filmbedekte tablet bevat amoksisillientrihidraat ekwivalent aan 875 mg amoksisillien en kaliumklavulanaat ekwivalent aan 125 mg klavuulaansuur. Suikervry.

Die ander bestanddele is mikrokristallyne sellulose, isopropielalkohol, magnesiumstearaat, metileenchloried, Opadry wit, kolloïdale anhidriese silika en natriumstyselglikolaat.

FARMAKOLOGIESE KLASSIFIKASIE:
A 20.1.2 Penisilliene

FARMAKOLOGIESE WERKING:
AURO AMOXICLAV is 'n kombinasie van amoksisillien en klavulaansuur.

Amoksisillien is 'n semisintetiese beta-laktamase vatbare penisillien wat *in vitro* bakteriedodende aktiwiteit teen 'n wye spektrum nie-beta-laktamaseproduserende gram-positiewe en gram-negatiewe organismes toon. Die spektrum van aktiwiteit sluit nie daardie organismes in wat beta-laktamase produseer nie, naamlik weerstandbiedende stafilokokke, en alle stamme van *Pseudomonas, Klebsiella* en *Enterobacter.*

Dit is aangetoon dat klavulaansuur *in vitro* '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 chromosoomgemedieerde (Sykes Tipe 1 kefalosporinase) beta-laktamases wat deur *Acinetobacter* spesies, *Citrobacter* spesies, *Enterobacter,* indool positiewe *Proteus, Providencia* spesies en *Serratia marcescens* geproduseer word, nie. *In vitro* het die formulasie sinergisme teen amoksisillienweerstandbiedende organismes getoon, met geen bewys van antagonisme nie, en die aktiwiteit het ook nie in die teenwoordigheid van serum afgeneem nie (*in vitro* aktiwiteit beteken nie noodwendig *in vivo* doeltreffendheid nie). Die klavulaansuurkomponent het baie min bakteriedodende aktiwiteit.

Farmakokinetika
Absorpsie:
Amoksisillien is stabiel in die teenwoordigheid van suur maagsekresies. Piek bloedvlakke word 1-2 ure na toediening bereik. Daar is 'n lineêre dosisrespons in piek serumvlakke.

Die farmakokinetika van amoksisillien en klavulaansuur is nou verwant en nie een van die middels word deur die teenwoordigheid van voedsel in die maag beïnvloed nie.

Verspreiding:
Ongeveer 18 % van die totale plasma-amoksisillieninhoud is proteïengebonde. Amoksisillien versprei maklik in die meeste liggaamsweefsels, met uitsondering van die brein en spinale vloeistof. Oor die algemeen laat inflammasie die deurlaatbaarheid van die meninges tot penisillien toeneem. Dit mag ook op amoksisillien van toepassing wees.

Uitskeiding:
Die eliminasiehalfleeftyd van amoksisillien is ongeveer 1 uur. Die medetoediening van probenesied het min effek op die uitskeiding van die klavulaansuurkomponent van die formulasie. Klein hoeveelhede amoksisillien word ook in die feses en gal uitgeskei.

INDIKASIES:
AURO AMOXICLAV formulasies word aangedui vir die behandeling van infeksies wat deur amoksisillienweerstandbiedende organismes wat beta-laktamases produseer, wat sensitief teen klavulaansuur is:
- Boonste lugweginfeksies, soos sinusitis, herhalende otitis media en tonsilitis.
- Benede lugweginfeksies, soos brongitis en brongopneumonie.
- Genito-urienweginfeksies, soos sistitis, uretritis, piëlonefritis.
- Vel- en sagte weefselinfeksies.

AURO AMOXICLAV formulasies sal ook doeltreffend wees in die behandeling van besmettings veroorsaak deur amoksisilliensensitiewe organismes teen die toepaslike amoksisilliendosis, aangesien die klavulaansuurkomponent nie in hierdie situasie tot die terapeutiese effek bydra nie.

KONTRA-INDIKASIES:
Hipersensitiwiteit teen penisillien of kefalosporiene. Kruissensitiwiteit tussen penisilliene en kefalosporiene is goed gedokumenteer. **AURO AMOXICLAV** word teenaangedui in pasiënte met 'n vorige geskiedenis van amoksisillien/klavulaansuurverwante geelsug/lewerdisfunksie.

WAARSKUWINGS EN SPESIALE VOORSORGSMAATREËLS:
Ernstige en soms fatale hipersensitiwiteitsreaksies (anafilakties) is aangemeld in pasiënte op penisillienterapie. Voordat terapie met **AURO AMOXICLAV** geïnisieer word, behoort noukeurige navraag gedoen te word na vorige hipersensitiwiteitsreaksies teen penisillien, kefalosporiene of ander allergene. Alhoewel anafilakse meer dikwels met parenterale terapie voorkom, het dit voorgekom in pasiënte op orale penisilliene. Die voorkoms van hierdie reaksies is meer waarskynlik in individue met 'n geskiedenis van hipersensitiwiteit teen penisillien en/of 'n geskiedenis van sensitiwiteit teen veelvuldige allergene. Daar bestaan vermeldings van indiwidue met 'n geskiedenis van hipersensitiwiteit teen penisillien, wat erge reaksies ondervind het nadat hulle met kefalosporiene behandel is.

Indien 'n allergiese reaksie voorkom, behoort **AURO AMOXICLAV** gestaak en die toepaslike terapie ingestel te word. In die geval van ernstige anafilaktiese reaksies mag onmiddellike noodbehandeling met adrenalien nodig wees. Suurstof, intraveneuse kortikosteroïede en lugwegbestuur, insluitende intubering mag ook nodig wees.

AURO AMOXICLAV behoort vermy te word wanneer besmetlike mononukleose vermoed word, aangesien die voorkoms van 'n morbillivorme uitslag na die gebruik van amoksisillien, met hierdie kondisie geassosieer is.

Pseudomembraneuse enterokolitis is aangemeld. Die moontlikheid van superinfeksies met mikotiese of bakteriese patogene behoort in gedagte gehou te word gedurende terapie. Indien superinfeksies ontwikkel (gewoonlik met *Aerobacter, Pseudomonas* of *Candida*), behoort die middel gestaak te word en/of toepaslike terapie behoort ingestel te word. Verlengde gebruik mag tot oorgroeiing van nie-vatbare organismes lei.

Verlenging van die protrombientyd is selde in pasiënte wat **AURO AMOXICLAV** ontvang het, aangemeld. Toepaslike monitering behoort toegepas te word wanneer antikoagulante terselfdertyd voorgeskryf word.

Verbygaande hepatitis en cholestatiese geelsug is aangemeld. **AURO AMOXICLAV** behoort met sorg in pasiënte met tekens van lewerdisfunksie gebruik te word.

AURO AMOXICLAV 1000 mg behoort nie in pasiënte met 'n glomerulêre filtrasietempo van minder as 30 ml/minuut gebruik te word nie.

Sorg behoort aan die dag gelê te word wanneer amoksisillien aan pasiënte met sifilis toegedien word, aangesien die Jarisch-Herxheimerreaksie in hierdie pasiënte mag voorkom.

Wanneer hoë dosisse toegedien word, moet voldoende vloeistofinname en urienuitset onderhou word. Die natriuminhoud moet in gedagte gehou word in pasiënte op 'n soutbeperkte dieet wanneer die toediening van hoë dosisse nodig is.

Periodieke evaluering van orgaansisteemfunksies, insluitende nier-, lewer- en hematopoïetiese funksie, word gedurende verlengde terapie aanbeveel. 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, weens die moontlikheid daarvan dat die onderliggende oorsaak besmetlike mononukleose is. Met laasgenoemde is daar 'n hoë insidens van uitslag wanneer amoksisillien gebruik word.

AURO AMOXICLAV behoort met sorg toegedien te word aan pasiënte met limfatiese leukemie, aangesien hulle veral vatbaar vir amoksisilliengeïnduseerde veluitslag is.

Belemmerde lewerfunksie:
Veranderinge in lewerfunksietoetse is waargeneem in sommige pasiënte wat **AURO AMOXICLAV** ontvang het. Dit behoort met sorg gebruik te word in pasiënte met erge lewerdisfunksie.

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

Gebruik gedurende laktasie:
Amoksisillien word in die melk uitgeskei; daar bestaan geen data oor die uitskeiding van klavulaansuur in menslike melk nie. Daarom behoort sorg aan die dag gelê te word wanneer **AURO AMOXICLAV** aan 'n sogende moeder toegedien word.

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

INTERAKSIES:
Probenesied verminder die buisuitskeiding van amoksisillien in die niere, maar beïnvloed nie die uitskeiding van klavulaansuur nie. Die gelyktydige gebruik saam met **AURO AMOXICLAV** mag lei tot 'n toename in en verlenging bloedvlakke van amoksisillien, maar nie van klavulaansuur nie.

AURO AMOXICLAV mag die doeltreffendheid van orale voorbehoedmiddels verminder en pasiënte behoort dienooreenkomstig gewaarsku te word.

Die gelyktydige toediening van allopurinol en ampisillien verhoog die voorkoms van veluitslag aansienlik in pasiënte wat beide middels ontvang, in teenstelling met pasiënte wat ampisillien alleen ontvang. Dit is onbekend of hierdie potensiëring van ampisillienuitslag die gevolg van allopurinol is nie, en of dit is weens die hiperurisemie wat in hierdie pasiënte teenwoordig is nie.

Tetrasikliene en ander bakteriostatiese middels mag met die bakteriedodende effekte van amoksisillien inmeng.

Interaksie met laboratoriumtoetse:
Dit word aanbeveel dat wanneer daar vir die teenwoordigheid van glukose in die urien gedurende behandeling met **AURO AMOXICLAV** getoets word, ensimaties glukose-oksidasemetodes gebruik word. Weens die hoë urienkonsentrasies van amoksisillien, kom vals-positiewe lesings dikwels met chemiese metodes voor.

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

Gebruik gedurende laktasie:
Amoksisillien word na die borsmelk versprei. Alhoewel geen noemenswaardige probleme in mense gedokumenteer is nie, mag die gebruik van amoksisillien deur sogende moeders tot sensitering, diarree, kandidiase en veluitslag in die baba lei.

DOSIS EN GEBRUIKSAANWYSINGS:
Vir orale formulasies:
Tablette behoort onmiddellik voor 'n maaltyd geneem te word.

Dosisse:
Algemene inligting: Vir infeksies veroorsaak deur amoksisilliensensitiewe organismes, is die dosis dié wat vir amoksisillien goedgekeur is, aangesien die klavulaansuurkomponent nie tot die terapeutiese effek bydra nie.

Volwassenes:
Die volwasse dosis **AURO AMOXICLAV** is een **AURO AMOXICLAV 375 mg** tablet elke 8 ure aan die begin van 'n maaltyd. Vir meer ernstige infeksies van die asemhalingstelsel, behoort die dosis een **AURO AMOXICLAV 625 mg** tablet elke 8 ure aan die begin van 'n maaltyd te wees, of een **AURO AMOXICLAV 1000 mg** tablet elke 12 ure aan die begin van 'n maaltyd.

Aangesien **AURO AMOXICLAV 375 mg, 625 mg** en **1000 mg** dieselfde hoeveelheid klavulaansuur bevat (125 mg as die kaliumsout) nie, is twee **AURO AMOXICLAV 375 mg** tablette nie ekwivalent aan een **AURO AMOXICLAV 625 mg** tablet nie, en is twee **AURO AMOXICLAV 625 mg** tablette nie ekwivalent aan een **AURO AMOXICLAV 1000 mg** tablet nie. Daarom behoort twee **AURO AMOXICLAV 375 mg** tablette nie in plaas van een **AURO AMOXICLAV 625 mg** vir meer ernstige infeksies gebruik te word nie. Netso behoort twee **AURO AMOXICLAV 625 mg** nie in plaas van een **AURO AMOXICLAV 1000 mg** tablet gebruik te word nie.

Belemmerde nierfunksie:
Beide amoksisillien en klavulaansuur word deur die niere uitgeskei en die serumhalfleeftyd van elk neem toe in pasiënte met belemmerde nierfunksie. Daarom mag dit nodig wees om die dosis te verminder of die dosisinterval te verleng. Dosisaanpassing word gebaseer op die maksimum aanbevole vlak van amoksisillien. Die volgende skedule word voorgestel:

AURO AMOXICLAV 375 mg, 625 mg:
- Geringe belemmering (kreatiniensuiwering meer as 30 ml/minuut): geen verandering in dosis nie.
- Matige belemmering (kreatiniensuiwering 10 tot 30 ml/minuut): 1 tablet elke 12 ure.
- Erge belemmering (kreatiniensuiwering minder as 10 ml/minuut): 'n halwe tablet elke 12 ure.

AURO AMOXICLAV 1000 mg behoort nie in pasiënte met 'n glomerulêre filtrasietempo van minder as 30 ml/minuut gebruik te word nie. Hemodialise verminder die serumkonsentrasies van beide amoksisillien en klavulaansuur en 'n bykomende dosis behoort aan die einde van dialise toegedien te word.

Dosisriglyn:
Amoksisilliensensitiewe organismes

Produk	Boonste lugweginfeksie (Otitis media)	Benede lugweginfeksie (Brongitis)	Urienweg- infeksie	Vel- en sagteweefsel-infeksie
AURO AMOXICLAV 375 mg	1 tablet elke 8 ure	-	1 tablet elke 8 ure	1 tablet elke 8 ure
AURO AMOXICLAV 625 mg	1 tablet elke 8 ure	1 tablet elke 8 ure	1 tablet elke 8 ure	1 tablet elke 8 ure
AURO AMOXICLAV 1000 mg	1 tablet elke 12 ure	1 tablet elke 12 ure	1 tablet elke 12 ure	1 tablet elke 12 ure

Amoksisillienweerstandbiedende organismes

Produk	Boonste lugweginfeksie	Benede lugweginfeksie	Urienweg- infeksie	Vel- en sagteweefsel-infeksie
AURO AMOXICLAV 375 mg	-	-	1 tablet elke 8 ure	1 tablet elke 8 ure
AURO AMOXICLAV 625 mg	1 tablet elke 8 ure	1 tablet elke 8 ure	1 tablet elke 8 ure	1 tablet elke 8 ure
AURO AMOXICLAV 1000 mg	1 tablet elke 12 ure	1 tablet elke 12 ure	1 tablet elke 12 ure	1 tablet elke 12 ure

Kinders:
Die dosis van **AURO AMOXICLAV** in kinders is 25 - 50 mg/kg/dag van die 4 dele amoksisillien, 1 deel klavulaansuurpreparaat (wat ooreenstem met die daaglikse dosis van die ekwivalent van 20 - 40 mg/kg amoksisillien en 5 - 10 mg/kg klavulaansuur, geneem in verdeelde dosisse elke agt ure, aan die begin van 'n maaltyd.

NEWE EFFEKTE
Die mees algemeen aangemelde newe effekte is diarree, naarheid, braking, indigestie, buikpyn, veluitslag, urtikarie en erythema multiforme, vaginitis, abnormale smaak, hoofpyn, duiseligheid, moegheid en warm gloede.

Die insidens en graad van erns van die newe effekte, veral naarheid en diarree, het met die hoër aanbevole dosis voorgekom en kan verminder 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 van amoksisillien vereis word, behoort oorweging aan die toediening van bykomende amoksisillien geskenk te word.

Die volgende newe effekte is aangemeld en mag met **AURO AMOXICLAV** voorkom:

Afwykings van die immuunsisteem:
Dikwels: Veluitslag, pruritus, urtikarie, serumsiekteagtige sindroom, erythema multiforme, Stevens-Johnson se sindroom, toksiese epidermale nekrolise.
Wanneer sulke simptome voorkom behoort **AURO AMOXICLAV** onttrek te word. Ernstige en soms fatale hipersensitiwiteitsreaksies (anafilakties) en angioneurotiese edeem mag met orale penisillien voorkom (sien **"WAARSKUWINGS EN SPESIALE VOORSORGSMAATREËLS"**).

Die volgende newe effekte is aangemeld en die frekwensies is onbekend: Interstisiële nefritis, hipersensitiwiteitsvaskulitis, bulleuse eksfoliatiewe dermatitis.

Gastroïntestinale afwykings:
Baie dikwels: Naarheid, braking, diarree.
Dikwels: Glossitis, swart-harige-tong, mukokutane kandidiase.

Die volgende newe effekte is aangemeld en die frekwensies is onbekend: Gastritis, stomatitis, enterokolitis en antibiotika geassosieerde kolitis (insluitende pseudomembraneuse kolitis en hemoragiese kolitis). Indien gastroïntestinale simptome voorkom, kan dit verminder word deur **AURO AMOXICLAV** aan die begin van 'n maaltyd te neem.

Hepatobileêre afwykings:
Dikwels: Hepatitis, cholestatiese geelsug.
Die simptome mag erg wees en kom hoofsaaklik in volwassenes of bejaarde pasiënte voor. Tekens en simptome kom gewoonlik gedurende of kort na behandeling voor. In sommige gevalle kom dit egter eers na 'n paar weke nadat behandeling gestaak is, voor.
Die hepatiese effekte is gewoonlik omkeerbaar. In baie uitsonderlike gevalle is dood egter aangemeld. Hierdie gevalle was byna altyd geassosieer met ernstige onderliggende siekte of meegaande medikasie.

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

Afwykings van die bloed- en limfsisteem:
Dikwels: Omkeerbare leukopenie.
Die volgende newe effekte is aangemeld en die frekwensies is onbekend: Hemolitiese anemie, verlenging van bloedings- en protrombientyd, omkeerbare trombositopenie, trombositopeniese purpura, eosinofilie, agranulositose. Hierdie reaksies is gewoonlik omkeerbaar met staking van terapie en daar word geglo dat dit 'n hipersensitiwiteitsfenomeen is. Toepaslike monitering behoort uitgevoer te word wanneer antikoagulante saam voorgeskryf word.

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

Algemene afwykings en afwykings by die plek van toediening:
Die volgende newe effekte is aangemeld en die frekwensies is onbekend: Oppervlakkige tandverkleuring, veral met die suspensie- en koutabletformulasies. Dit kan gewoonlik met behulp van borsel verwyder word.

Ondersoeke:
'n Matige toename in aspartaattransaminase (AST) en/of alanientransaminase (ALT) is in pasiënte wat met **AURO AMOXICLAV** behandel is, waargeneem. Die betekenis van hierdie bevindinge is egter onbekend. 'n Geringe trombositose is in minder as 1 % van pasiënte wat met **AURO AMOXICLAV** behandel is, waargeneem.

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. Die simptome van water- en elektrolietwanbalans behoort simptomaties behandel te word.

Voldoende vloeistofinname en urienuitset behoort onderhou te word om die voorkoms van kristalurie tot 'n minimum te beperk

Amoksisillien kan met behulp van hemodialise uit die sirkulasie verwyder word. Die molekulêre massa, graad van proteïenbinding en farmakokinetiese profiel van klavulaansuur, saam met die inligting van 'n enkele pasiënt met belemmerde nierfunksie wil daarop dui dat hierdie middel ook met hemodialise verwyder kan word.

IDENTIFIKASIE:

AURO AMOXICLAV 375 mg:
Wit, ovaalvormige, filmbedekte tablette, met 'A' op die een kant en '63' op die ander kant daarop gedruk.

AURO AMOXICLAV 625 mg:
Wit, ovaalvormige, filmbedekte tablette, met 'A' op die een kant en '64' op die ander kant daarop gedruk.

AURO AMOXICLAV 1000 mg:
Wit, kapsuulvormige, filmbedekte tablette, met 'A' op die een kant daarop gedruk, en 'n breeklyn tussen die '6' en '5' op die anderkant.

AANBIEDING:

AURO AMOXICLAV 375 mg:
Tablette word in 25 mikron poliamied / 45 mikron aluminiumfoelie / 60 mikron PVC film as die vormingsmateriaal, met 25 mikron gedrukte aluminiumfoelie as dekmateriaal, verpak. Elke stolp bevat 5 tablette.
Pakgrootte: 15s: Elke karton bevat 3 stolpverpakkings van 5 tablette elk.
Pakgrootte: 100s: Elke karton bevat 20 stolpverpakkings van 5 tablette elk.

AURO AMOXICLAV 625 mg:
Tablette word in 25 mikron poliamied / 45 mikron aluminiumfoelie / 60 mikron PVC film as die vormingsmateriaal, met 25 mikron gedrukte aluminiumfoelie as dekmateriaal, verpak. Elke stolp bevat 5 tablette.
Pakgrootte: 15s: Elke karton bevat 3 stolpverpakkings van 5 tablette elk.

AURO AMOXICLAV 1000 mg:
1. Tablette word in 25 mikron poliamied / 45 mikron aluminiumfoelie / 60 mikron PVC film as die vormingsmateriaal, met 25 mikron gedrukte aluminiumfoelie as dekmateriaal, verpak. Elke stolp bevat 5 tablette.
Pakgrootte: 10s: Elke karton bevat 2 stolpverpakkings van 5 tablette elk.
2. Tablette word in gedrukte 40 mikron aluminiumfoelie gelamineer met 150-maat poli aan die een kant en ongedrukte 40 mikron aluminiumfoelie gelamineer met 150-maat poli aan die ander kant, verpak. Elke strokie bevat 10 tablette.
Pakgrootte: 10s: Een strokie met 10 tablette.

BERGINGSINSTRUKSIES:
Bewaar by of benede 30 °C. Moenie stolpverpakking uit die karton verwyder tot voor gebruik nie.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:
SUID-AFRIKA:
AURO AMOXICLAV 375 mg: 41/20.1.2/0535
AURO AMOXICLAV 625 mg: 41/20.1.2/0536
AURO AMOXICLAV 1 000 mg 41/20.1.2/0537

NAMIBIË:
AURO AMOXICLAV 375 mg: 10/20.1.2/0250
AURO AMOXICLAV 625 mg: 10/20.1.2/0251
AURO AMOXICLAV 1 000 mg 10/20.1.2/0252

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE:
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27 Februarie 2022

DETACH BEFORE DISPENSING

SUID-AFRIKA: **S4**

NAMIBIË: **NS2**

AURO AMOXICLAV 375 mg (tablet)
AURO AMOXICLAV 625 mg: (tablet)
AURO AMOXICLAV 1000 mg: (tablet)
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 te 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 375 mg:
Elke filmbedekte tablet bevat amoksisillientrihidraat ekwivalent aan 250 mg amoksisillien en kaliumklavulanaat ekwivalent aan 125 mg klavuulaansuur. Suikervry.

AURO AMOXICLAV 625 mg:
Elke filmbedekte tablet bevat amoksisillientrihidraat ekwivalent aan 500 mg amoksisillien en kaliumklavulanaat ekwivalent aan 125 mg klavuulaansuur. Suikervry.

AURO AMOXICLAV 1000 mg:
Elke filmbedekte tablet bevat amoksisillientrihidraat ekwivalent aan 875 mg amoksisillien en kaliumklavulanaat ekwivalent aan 125 mg klavuulaansuur. Suikervry.

Die ander bestanddele is mikrokristallyne sellulose, isopropielalkohol, magnesiumstearaat, metileenchloried, Opadry wit, kolloïdale anhidriese silika en natriumstyselglikolaat.

2. WAARVOOR AURO AMOXICLAV GEBRUIK WORD

AURO AMOXICLAV formulasies word gebruik vir die behandeling van infeksies wat deur amoksisillienweerstandbiedende organismes wat beta-laktamase produseer wat sensitief teen klavulaansuur is, veroorsaak word.

- Boonste lugweginfeksies soos sinusitis, herhalende otitis media, tonsilitis.
- Benede lugweginfeksies soos bronchitis en bronchopneumonie.
- Genito-urienweginfeksies soos sistitis, uretritis, piëlonefritis.
- Vel- en sagteweefselinfeksies.

AURO AMOXICLAV formulasies sal ook teen die toepaslike amoksisilliendosis, effektief in die behandeling van infeksies wat deur amoksisilliensensitiewe organismes veroorsaak word, wees aangesien die klavulaansuurkomponent nie tot die terapeutiese effek bydra nie.

3. VOORDAT U AURO AMOXICLAV NEEM

Moenie AURO AMOXICLAV neem nie:
- As u hipersensitief (allergies) teen penisillien of kefalosporiene of enige van die bestanddele van **AURO AMOXICLAV** is.
- As u 'n geskiedenis van amoksisillien/klavulaansuurgeassosieerde lewerdisfunksie het.

Neem spesiale sorg met AURO AMOXICLAV:
- As 'n allergiese reaksie voorkom, behoort **AURO AMOXICLAV** onmiddellik gestaak en die toepaslike terapie ingestel te word.
- **AURO AMOXICLAV** behoort vermy te word as besmetlike mononukleose vermoed word.
- Periodieke evaluering van orgaanfunksie, insluitende nier-, lewer- en hematopoëtiese funksies word met langdurige terapie aangeraai.
- As u aan 'n nier- of lewersiekte ly.
- As u aan sifilis ly.
- Wanneer hoë dosisse toegedien word, moet voldoende vloeistofinname en urienuitset gehandhaaf word.
- Die natriuminhoud behoort in pasiënte op 'n natriumbeperkte dieet in gedagte gehou te word as die toediening van hoë dosisse nodig is.
- Periodieke evaluering van orgaanfunksie, insluitende nier-, lewer- en hematopoëtiese funksies word met langdurige terapie aangeraai.
- As u aan 'n nier- of lewersiekte ly. Aangesien **AURO AMOXICLAV** amoksisillien, 'n aminopenisillien bevat, is dit nie die behandeling van keuse in pasiënte wat met 'n seer keel of faringitis presenteer nier, aangesien die moontlikheid bestaan dat die onderliggende oorsaak besmetlike mononukleose is. In die teenwoordigheid van besmetlike mononukleose is daar 'n hoë insidens van uitslag as amoksisillien gebruik word. **AURO AMOXICLAV** behoort met sorg aan pasiënte met limfatiese leukemie gegee word aangesien hulle veral vatbaar vir amoksisilliengeïnduseerde veluitslag is.

Swangerskap en borsvoeding:

Gebruik gedurende swangerskap:
Die veiligheid van **AURO AMOXICLAV** in swangerskap is nie vasgestel nie.

Gebruik gedurende laktasie:
Amoksisillien word in borsmelk versprei. Alhoewel beduidende probleme in mense nie gedokumenteer is nie, kan die gebruik van amoksisillien deur sogende moeders tot sensitering, diaree, kandidiase en veluitslag in die baba lei.

As u swanger is of u baba borsvoed, moet u asseblief u dokter, apteker of ander professionele gesondheidsbeampte vir advies nader.

Die neem van ander medisyne saam met AURO AMOXICLAV:
Daar bestaan interaksies tussen **AURO AMOXICLAV** en probenesied, orale voorbehoedmiddels en tetrasikliene.

Daar word aanbeveel dat gedurende behandeling met **AURO AMOXICLAV**, ensimatiese oksidasemetodes gebruik behoort te word wanneer vir die teenwoordigheid van glukose in die urien getoets word. Weens die hoë urienkonsentrasies van amoksisillien, kom vals-positiewe resultate dikwels met chemiese metodes voor.

Stel altyd u professionele gesondheidsbeampte in kennis as u enige ander medisyne gebruik. (Dit sluit komplementêre of 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.

Vir orale formulasies:
Tablette behoort onmiddellik voor 'n maaltyd geneem te word.

Dosering:
Algemene inligting: Vir infeksies wat deur amoksisilliensensitiewe organismes veroorsaak word, is die dosis soos vir amoksisillien goedgekeur, aangesien die klavulaansuurkomponent nie tot die terapeutiese effek bydra nie.

Volwassenes:
Die volwasse dosis van **AURO AMOXICLAV** is een **AURO AMOXICLAV 375 mg** tablet elke agt ure voor 'n maaltyd. Vir meer ernstige infeksies en lugweginfeksies behoort die dosis een **AURO AMOXICLAV 625 mg** tablet elke agt ure voor 'n maaltyd te wees, of een **AURO AMOXICLAV 1000 mg** tablet elke twaalf ure voor 'n maaltyd.

Aangesien **AURO AMOXICLAV 375 mg, 625 mg** en **1000 mg** dieselfde hoeveelheid klavulaansuur bevat (125 mg as die kaliumsout), is twee **AURO AMOXICLAV 325 mg** tablette nie ekwivalent aan een **AURO AMOXICLAV 625 mg** tablet nie, en twee **AURO AMOXICLAV 625 mg** tablette nie ekwivalent aan een **AURO AMOXICLAV 1000 mg** tablet nie. Daarom behoort twee **AURO AMOXICLAV 375 mg** tablette nie met een **AURO AMOXICLAV 625 mg** tablet vervang te word nie, en ook nie twee **AURO AMOXICLAV 625 mg** tablette met een **AURO AMOXICLAV 1000 mg** tablet vir die behandeling van meer ernstige infeksies nie.

Ingekorte nierfunksie:
Beide amoksisillien en klavulaansuur word deur die niere uitgeskei en die serumhalfleeftyd van beide neem toe met nierversaking. Daarom kan die dosis moontlik verlaag of die interval tussen dosisse verleng word.

Dosisaanpassings word gebaseer op die maksimum aanbevole vlak van amoksisillien. Die volgende skedule word voorgestel:

AURO AMOXICLAV 375 mg, 625 mg:
- Geringe inkorting (kreatiniensuiwering meer as 30 ml/min): geen verandering in dosis nie.
- Matige inkorting (kreatiniensuiwering 10 tot 30 ml/min): 1 tablet elke 12 ure.
- Erge inkorting (kreatiniensuiwering minder as 30 ml/min: 'n halwe tablet elke 12 ure.

AURO AMOXICLAV 1000 mg behoort nie in pasiënte met 'n glomerulêre filtrasiekoers van minder as 30 ml/min gebruik te word nie.

Hemodialise verminder die serumkonsentrasies van beide amoksisillien en klavulaansuur en 'n bykomende dosis behoort aan die einde van dialise toegedien te word.

Doseringsgids:
Amoksisilliensensitiewe organismes

Produk	Boonste lugweg-infeksie	Benede lugweg-infeksie	Urienweg-infeksie	Vel- en sagte weefselinfeksie
AURO AMOXICLAV 375 mg	1 tablet elke 8 ure	-	1 tablet elke 8 ure	1 tablet elke 8 ure
AURO AMOXICLAV 625 mg	1 tablet elke 8 ure	1 tablet elke 8 ure	1 tablet elke 8 ure	1 tablet elke 8 ure
AURO AMOXICLAV 1000 mg	1 tablet elke 12 ure	1 tablet elke 12 ure	1 tablet elke 12 ure	1 tablet elke 12 ure

Amoksisillienweerstandbiedende organismes

Produk	Boonste lugweg-infeksie	Benede lugweg-infeksie	Urienweg-infeksie	Vel- en sagte weefselinfeksie
AURO AMOXICLAV 375 mg	-	-	1 tablet elke 8 ure	1 tablet elke 8 ure
AURO AMOXICLAV 625 mg	1 tablet elke 8 ure	1 tablet elke 8 ure	1 tablet elke 8 ure	1 tablet elke 8 ure
AURO AMOXICLAV 1000 mg	1 tablet elke 12 ure	1 tablet elke 12 ure	1 tablet elke 12 ure	1 tablet elke 12 ure

Kinders:
Die dosis van **AURO AMOXICLAV** in kinders is 25 – 50 mg/kg/dag van die 4 dele amoksisillien, 1 deel klavulaansuurpreparate (wat ooreenstem met 'n daaglikse dosis ekwivalent aan 20 – 40 mg/kg amoksisillien en 5 – 10 mg/kg klavulaansuur), geneem in verdeelde dosisse elke agt ure, voor 'n maaltyd.

As u te veel AURO AMOXICLAV geneem het:
Oordosering met amoksisillien is gewoonlik asimptomaties. Gastroïntestinale effekte soos naarheid, braking en diaree kan voorkom en die simptome van water- en elektrolietwanbalans behoort simptomaties behandel te word.

Voldoende vloeistofinname en urienuitset moet gehandhaaf 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, asook inligting van 'n enkel pasiënt met ingekorte nierfunksie wil alles daarop dui dat hierdie middel ook deur hemodialise verwyder kan word.

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:

Moenie 'n dubbel dosis neem om vir 'n oorgeslaande dosis op te maak nie.

5. MOONTLIKE NEWE EFFEKTE

AURO AMOXICLAV kan newe effekte hê.

Die mees dikwels aangemelde newe effekte is diaree, naarheid, braking, indigestie, buikpyn, veluitslag urtikarie en erythema multiforme, vaginitis, abnormale smaak, hoofpyn, duiseligheid, moegheid en warm gloede.

Die insidens en graad van erns van die newe effekte, veral naarheid en diaree, het met die hoër aanbevole dosis toegeneem en kan tot 'n minimum beperk word deur **AURO AMOXICLAV** aan die begin van 'n maaltyd toe te dien. Boonop, aangesien hierdie simptome veral aan die kaliumklavulanaatkomponent gekoppel word, waar hierdie gastroïntestinale simptome voorkom en 'n hoër konsentrasie van amoksisillien vereis word, behoort oorweging aan die toediening van bykomende aparte amoksisillien gegee te word.

Die volgende newe effekte is aangemeld en kan met **AURO AMOXICLAV** voorkom:

Hipersensitiwiteitsreaksies:
Veluitslag, pruritus en urtikarie, serumsiekte-agtige sindroom, erythema multiforme, selde voorkomende gevalle van Stevens-Johnson se sindroom, hipersensitiwiteitsvaskulitis en minder dikwels bulleuse eksfoliatiewe dermatitis en toksiese epidermale nekrolise is aangemeld. Wanneer sulke reaksies voorkom, behoort die gebruik van **AURO AMOXICLAV** gestaak te word. Ernstige en af en toe fatale hipersensitiwiteit (anafilakties) en angioneurotiese edeem kan met orale penisillien voorkom.
Interstisiële nefritis kan af en toe voorkom.

Gastroïntestinale afwykings:
Naarheid, braking, diaree, gastritis, stomatitis, glossitis, swart "harige" tong, enterokolitis, mukokutane kandidiase en antibiotikageassosieerde kolitis (insluitende pseudomembraneuse kolitis en hemoragiese kolitis). As gastroïntestinale reaksies voorkom, kan hulle verminder word deur **AURO AMOXICLAV** aan die begin van 'n maaltyd te neem.

Lewereffekte:
Hepatitis en cholestatiese geelsug is aangemeld. Die gevalle kan ernstig wees en kom hoofsaaklik in volwassenes of bejaarde pasiënte voor. Die tekens en simptome kom gewoonlik gedurende of kort na behandeling voor. In sommige gevalle kan dit egter eers na etlike weke nadat met die behandeling gestaak is, te voorskyn kom.
Die lewereffekte is gewoonlik omkeerbaar. Die dood is egter in uitsonderlike gevalle aangemeld. Hierdie gevalle was byna altyd met ernstige onderliggende siekte of meegaande medikasie geassosieer.
'n Matige verhoging in aspartaattransaminase (AST) en/of alanientransaminase (ALT) is waargeneem in pasiënte wat met **AURO AMOXICLAV** behandel is, maar die belang van hierdie bevindings is nie bekend nie.

Niereffekte:
Kristalurie is aangemeld.

Hematologiese effekte:
Hemolitiese anemie, omkeerbare trombositopenie, trombositopeniese purpura, eosinofilie, omkeerbare leukopenie en agranulositose is aangemeld. Hierdie reaksies is gewoonlik omkeerbaar met staking van terapie en daar word geglo dat dit 'n hipersensitiwiteit is. 'n Geringe trombositose is in minder as 1 % van die pasiënte wat met **AURO AMOXICLAV** behandel is, aangemeld. Verlenging van bloei- en protrombientyd is ook minder dikwels aangemeld. Toepaslike monitering behoort onderneem te word wanneer teenstolmiddels gelyktydiglik toegedien word.

Sentrale Senuweestelsel (SSS)-effekte:
SSS-effekte kom baie selde voor. Dit sluit omkeerbare hiperaktiwiteit, duiseligheid, hoofpyn en stuipaanvalle in. Stuipaanvalle kan met ingekorte nierfunksie of in diegene wat hoë dosisse ontvang, voorkom.

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 hierdie medisyne neem, moet u asseblief u dokter, apteker of ander professionele gesondheidsbeampte om advies raadpleeg.

6. OPBERGING EN WEGDOEN VAN AURO AMOXICLAV

Berg alle medisyne buite die bereik van kinders.

Bewaar teen of benede 30 °C.

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 375 mg:
Tablette word in 25 mikron poliamied/45 mikron aluminiumfoelie/60 mikron PVC film as die vormingsmateriaal en 25 mikron gedrukte aluminiumfoelie as dekkingsmateriaal verpak. Elke stolpstrokie bevat 5 tablette
Pakgrootte: 15s: Elke karton bevat 3 stolpstrokies van 5 tablette elk.
Pakgrootte: 100s: Elke karton bevat 20 stolpstrokies van 5 tablette elk.

AURO AMOXICLAV 625 mg:
Tablette word in 25 mikron poliamied/45 mikron aluminiumfoelie/60 mikron PVC film as die vormingsmateriaal en 25 mikron gedrukte aluminiumfoelie as dekkingsmateriaal verpak. Elke stolpstrokie bevat 5 tablette
Pakgrootte: 15s: Elke karton bevat 3 stolpstrokies van 5 tablette elk.

AURO AMOXICLAV 1000 mg:
1. Tablette word in 25 mikron poliamied/45 mikron aluminiumfoelie/60 mikron PVC film as die vormingsmateriaal en 25 mikron gedrukte aluminiumfoelie as dekkingsmateriaal verpak. Elke stolpstrokie bevat 5 tablette
Pakgrootte: 10s: Elke karton bevat 2 stolpstrokies van 5 tablette elk.
2. Tablette word in gedrukte 40 mikron aluminiumfoelie, gelamineer met 150-maat poli aan die een kant en ongedrukte aluminiumfoelie, gelamineer met 150-maat poli aan die ander kant verpak. Elke stolpstrokie bevat 10 tablette
Pakgrootte: 10s: Een stolpstrokie bevat 10 tablette

8. IDENTIFIKASIE VAN AURO AMOXICLAV

AURO AMOXICLAV 375 mg:
Wit, ovaalvormige filmbedekte tablette met 'A' op die een kant en '63' op die ander gedruk.

AURO AMOXICLAV 625 mg:
Wit, ovaalvormige filmbedekte tablette met 'A' op die een kant en '64' op die ander gedruk.

AURO AMOXICLAV 1000 mg:
Wit, kapsulevormige filmbedekte tablette met 'A' op die een kant en '6' en '5' aan weerskante van die breeklyn op die ander kant gedruk.

9. REGISTRASIENOMMER

SUID-AFRIKA
AURO AMOXICLAV 375 mg: 41/20.1.2/0535
AURO AMOXICLAV 625 mg: 41/20.1.2/0536
AURO AMOXICLAV 1000 mg: 41/20.1.2/0537

NAMIBIË
AURO AMOXICLAV 375 mg: 10/20.1.2/0250
AURO AMOXICLAV 625 mg: 10/20.1.2/0251
AURO AMOXICLAV 1000 mg: 10/20.1.2/0252

10. NAAM EN ADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE

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 VAN DIE VOUBILJET
Datum van registrasie:
15 Augustus 2008

Datum van hersiening:
27 Februarie 2022

AURO AMOXICLAV
P1530564

AURO AMOXICLAV
P1530564

APPROVED
leshania , 2022/03/10 ,13:33:50

SCHEDULING STATUS

SOUTH AFRICA: S4

NAMIBIA: NS2

PROPRIETARY NAME (and dosage form):
AURO AMOXICLAV 375 mg (tablet)
AURO AMOXICLAV 625 mg (tablet)
AURO AMOXICLAV 1 000 mg (tablet)

COMPOSITION:
AURO AMOXICLAV 375 mg:
Each film-coated tablet contains amoxicillin trihydrate equivalent to 250 mg amoxicillin, and potassium clavulanate equivalent to 125 mg clavulanic acid. Sugar free.

AURO AMOXICLAV 625 mg:
Each film-coated tablet contains amoxicillin trihydrate equivalent to 500 mg amoxicillin, and potassium clavulanate equivalent to 125 mg clavulanic acid. Sugar free.

AURO AMOXICLAV 1 000 mg:
Each film-coated tablet contains amoxicillin trihydrate equivalent to 875 mg amoxicillin, and potassium clavulanate equivalent to 125 mg clavulanic acid. Sugar free.

The other ingredients are cellulose microcrystalline, isopropyl alcohol, magnesium stearate, methylene chloride, Opadry white, silica colloidal anhydrous and sodium starch glycolate.

PHARMACOLOGICAL CLASSIFICATION:
A 20.1.2 Penicillins

PHARMACOLOGICAL ACTION:

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). The clavulanic acid component has very little bactericidal action.

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. Co-administration of probenecid has little effect on the excretion of the clavulanic acid component of the formulation. 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, tonsilitis.
- 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 cephalosporin is well documented.
AURO AMOXICLAV is contra-indicated in patients with a previous history of amoxicillin/clavulanic-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 incubation 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.

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.

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.

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

AURO AMOXICLAV 1000 mg should not be used in patients with a glomerular filtration rate of less than 30 ml/minute.

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.

Periodic assessment of organ system functions, including renal, hepatic and haematopoietic function, is advisable during prolonged therapy. 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 leukaemia since they are especially susceptible to amoxicillin induced skin rashes.

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 appropriateness of therapy.

INTERACTIONS:

Probenecid decreases the renal tubular secretion of amoxicillin, but does not affect clavulanic acid excretion. Concurrent use with **AURO AMOXICLAV** may result in increased and prolonged blood levels of amoxicillin, but not of clavulanic acid.

AURO AMOXICLAV may reduce the efficacy of oral contraceptives and patients should be warned accordingly.

The concomitant administration of allopurinol and ampicillin 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 amoxicillin by nursing mothers may lead to sensitisation, diarrhoea, candidiasis and skin rash in the infant.

DOSAGE AND DIRECTIONS FOR USE:
For Oral Formulations:
Tablets should be taken immediately before a meal.

Dosages:
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:
The adult dose of **AURO AMOXICLAV** is one **AURO AMOXICLAV 375 mg** tablet every eight hours at the start of a meal. For more severe infections and infection of the respiratory tract, the dose should be one **AURO AMOXICLAV 625 mg** tablet every eight hours at the start of a meal, or one **AURO AMOXICLAV 1000 mg** tablet every 12 hours at the start of a meal.

Since **AURO AMOXICLAV 375 mg, 625 mg and 1000 mg** tablets contain the same amount of clavulanic acid (125 mg as the potassium salt) two **AURO AMOXICLAV 325 mg** tablets are not equivalent to one **AURO AMOXICLAV 625 mg** tablet, and two **AURO AMOXICLAV 625 mg** tablets are not equivalent to one **AURO AMOXICLAV 1000 mg.** Therefore, two **AURO AMOXICLAV 375 mg** tablets should not be substituted for one **AURO AMOXICLAV 625 mg** tablet or two **AURO AMOXICLAV 625 mg** tablets for one **AURO AMOXICLAV 1 000 mg** tablet for the treatment of more severe infections.

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. The following schedule is proposed:

AURO AMOXICLAV 375 mg, 625 mg:
- Mild impairment (creatinine clearance greater than 30 ml/minute): no change in dosage.
- Moderate impairment (creatinine clearance 10 to 30 ml/minute): 1 tablet every 12 hours.
- Severe impairment (creatinine clearance less than 10 ml/minute): half a tablet every 12 hours.

AURO AMOXICLAV 1 000 mg should not be used in patients with glomerular filtration rate of less than 30 ml/minute.
Haemodialysis decreases serum concentrations of both amoxicillin and clavulanic acid and an additional dose should be administered at the end of dialysis.

Dosage Guide:

Amoxicillin-Sensitive Organisms

Product	Upper Respiratory Tract Infection (Otitis media)	Lower Respiratory Tract Infection (Bronchitis)	Urinary Test infection	Skin & Soft Tissue infections
AURO AMOXICLAV 375 mg	1 tablet 8 hourly	—	1 tablet 8 hourly	1 tablet 8 hourly
AURO AMOXICLAV 625 mg	1 tablet 8 hourly	1 tablet 8 hourly	1 tablet 8 hourly	1 tablet 8 hourly
AURO AMOXICLAV 1 000 mg	1 tablet 12 hourly	1 tablet 12 hourly	1 tablet 12 hourly	1 tablet 12 hourly

Amoxicillin-Resistant Organisms

Product	Upper Respiratory Tract Infection	Lower Respiratory Tract Infection	Urinary Tract Infection	Skin &Soft Tissue infections
AURO AMOXICLAV 375 mg	—	—	1 tablet 8 hourly	1 tablet 8 hourly
AURO AMOXICLAV 625 mg	1 tablet 8 hourly	1 tablet 8 hourly	1 tablet 8 hourly	1 tablet 8 hourly
AURO AMOXICLAV 1 000 mg	1 tablet 12 hourly	1 tablet 12 hourly	1 tablet 12 hourly	1 tablet 12 hourly

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.

If you take more AURO AMOXICLAV than you should:
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.

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

SIDE EFFECTS:
The most frequently reported adverse effects are diarrhoea, nausea, vomiting, indigestion, abdominal pain, skin rashes, urticaria and erythema multiforme, vaginitis, abnormal taste, headache, dizziness, tiredness and hot flushes.

The incidence and severity of adverse effects, particularly nausea and diarrhoea, increased 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:**

Hypersensitivity reactions:
Skin rashes, pruritus and urticaria, serum sickness-like syndrome, erythema multiforme, rare cases of Stevens-Johnson syndrome, hypersensitivity vasculitis and less frequently bullous exfoliative dermatitis 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.
Interstitial nephritis can occur rarely.

Gastrointestinal reactions:
Nausea, vomiting, diarrhoea, gastritis, stomatitis, glossitis, black 'hairy' tongue, enterocolitis, mucocutaneous candidiasis and antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis). If gastrointestinal reactions are evident, they may be reduced by taking **AURO AMOXICLAV** at the start of a meal.

Hepatic effects:
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.**

Renal effects:
Crystalluria has been reported

Haematological effects:
Haemolytic anaemia, reversible thrombocytopenia, thrombocytopenic purpura, eosinophilia, reversible leucopenia and agranulocytosis 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.

Central Nervous System (CNS) effects:
CNS effects have been seen rarely. These include reversible hyperactivity, dizziness, headache and convulsions. Convulsions may occur with impaired renal function or in those receiving high doses.

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 this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

STORING AND DISPOSING OF AURO AMOXICLAV

Store all medicines out of the reach of children.
Store at or below 30 °C.

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

PRESENTATION OF AURO AMOXICLAV

AURO AMOXICLAV 375 mg:
Tablets are packed in 25 micron polyamide /45 micron aluminium foil / 60 micron PVC film as the forming material and 25 micron printed aluminium foil as the lidding material.
Each blister contains 5 tablets.
Pack size: 15s: Each carton contains 3 blisters of 5 tablets each.
Pack size: 100s: Each carton contains 20 blisters of 5 tablets each.

AURO AMOXICLAV 625 mg:
Tablets are packed in 25 micron polyamide /45 micron aluminium foil / 60 micron PVC film as the forming material and 25 micron printed aluminium foil as the lidding material.
Each blister contains 5 tablets.
Pack size: 15s: Each carton contains 3 blisters of 5 tablets each.

AURO AMOXICLAV 1000 mg:
1. Tablets are packed in 25 micron polyamide / 45 micron aluminium foil / 60 micron PVC film as the forming material and 25 micron printed aluminium foil as the lidding material.
   Each blister contains 5 tablets.
   Pack size: 10s: Each carton contains 2 blisters of 5 tablets each.
2. Tablets are packed in printed 40 micron aluminium foil laminated with 150-gauge poly on one side and plain 40 micron aluminium foil laminated with 150-gauge poly on other side. Each strip contains 10 tablets.
   Pack size: 10s: One strip pack containing 10 tablets.

IDENTIFICATION OF AURO AMOXICLAV

AURO AMOXICLAV 375 mg:
White oval shaped film-coated tablets, debossed with 'A' on one side and '63' on the other side

AURO AMOXICLAV 625 mg:
White oval shaped film-coated tablets, debossed with 'A' on one side and '64' on the other side.

AURO AMOXICLAV 1000 mg:
White coloured, capsule shaped, film-coated tablets, debossed with 'A' on one side and with a score line in between '6' and '5' on the other side.

REGISTRATION NUMBER:

SOUTH AFRICA
AURO AMOXICLAV 375 mg: 41/20.1.2/0535
AURO AMOXICLAV 625 mg: 41/20.1.2/0536
AURO AMOXICLAV 1 000 mg: 41/20.1.2/0537

NAMIBIA
AURO AMOXICLAV 375 mg: 10/20.1.2/0250
AURO AMOXICLAV 625 mg: 10/20.1.2/0251
AURO AMOXICLAV 1 000 mg: 10/20.1.2/0252

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
AUROGEN SOUTH AFRICA (PTY) LTD.
Woodhill Office Park, Building 1, First Floor
53 Phillip Engelbrecht Avenue
Meyersdal, Ext. 12, 1448
Johannesburg, South Africa

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DETACH BEFORE DISPENSING

SOUTH AFRICA: S4

NAMIBIA: NS2

AURO AMOXICLAV 375 mg (tablet)
AURO AMOXICLAV 625 mg (tablet)
AURO AMOXICLAV 1000 mg (tablet)
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 375 mg:
Each film-coated tablet contains amoxicillin trihydrate equivalent to 250 mg amoxicillin, and potassium clavulanate equivalent to 125 mg clavulanic acid. Sugar free.

AURO AMOXICLAV 625 mg:
Each film-coated tablet contains amoxicillin trihydrate equivalent to 500 mg amoxicillin, and potassium clavulanate equivalent to 125 mg clavulanic acid. Sugar free.

AURO AMOXICLAV 1000 mg:
Each film-coated tablet contains amoxicillin trihydrate equivalent to 875 mg amoxicillin, and potassium clavulanate equivalent to 125 mg clavulanic acid. Sugar free.

The other ingredients are cellulose microcrystalline, isopropyl alcohol, magnesium stearate, methylene chloride, Opadry white, silica colloidal anhydrous and sodium starch glycolate.

2. WHAT AURO AMOXICLAV IS USED FOR

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, tonsilitis.
- 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.

3. BEFORE YOU TAKE AURO AMOXICLAV

Do not take AURO AMOXICLAV:
- If you are hypersensitive (allergic) to penicillins or cephalosporins, or any of the ingredients of **AURO AMOXICLAV.**
- If you have a previous history of amoxicillin/clavulanic acid-associated liver dysfunction.

Take special care with AURO AMOXICLAV:
- If an allergic reaction occurs, **AURO AMOXICLAV** should be discontinued and the appropriate therapy instituted.
- **AURO AMOXICLAV** should be avoided if infectious mononucleosis is suspected.
- Periodic assessment of organ function, including renal, hepatic and haematopoietic function is advisable during prolonged therapy.
- If you suffer from kidney or liver disease.
- If you have syphilis.
- 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.
- Periodic assessment of organ system functions, including renal, hepatic and haematopoietic function, is advisable during prolonged therapy. 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 leukaemia since they are especially susceptible to amoxicillin induced skin rashes.

Pregnancy and Breastfeeding:

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 amoxicillin by nursing mothers may lead to sensitisation, diarrhoea, candidiasis and skin rash in the infant.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

Taking other medicines with AURO AMOXICLAV:
AURO AMOXICLAV interacts with probenecid, oral contraceptives, tetracyclines.
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.

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.

For oral formulations:
Tablets should 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.

Adults:
The adult dose of **AURO AMOXICLAV** is one **AURO AMOXICLAV 375 mg** tablet every eight hours at the start of a meal. For more severe infections and infection of the respiratory tract, the dose should be one **AURO AMOXICLAV 625 mg** tablet every eight hours at the start of a meal, or one **AURO AMOXICLAV 1000 mg** tablet every 12 hours at the start of a meal.

Since **AURO AMOXICLAV 375 mg, 625 mg and 1000 mg** tablets contain the same amount of clavulanic acid (125 mg as the potassium salt) two **AURO AMOXICLAV 325 mg** tablets are not equivalent to one **AURO AMOXICLAV 625 mg** tablet, and two **AURO AMOXICLAV 625 mg** tablets are not equivalent to one **AURO AMOXICLAV 1000 mg.** Therefore, two **AURO AMOXICLAV 375 mg** tablets should not be substituted for one **AURO AMOXICLAV 625 mg** tablet or two **AURO AMOXICLAV 625 mg** tablets for one **AURO AMOXICLAV 1000 mg** tablet for the treatment of more severe infections.

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. The following schedule is proposed:

AURO AMOXICLAV 375 mg, 625 mg:
- Mild impairment (creatinine clearance greater than 30 ml/minute): no change in dosage.
- Moderate impairment (creatinine clearance 10 to 30 ml/minute): 1 tablet every 12 hours.
- Severe impairment (creatinine clearance less than 30 ml/minute): half a tablet every 12 hours.

AURO AMOXICLAV 1000 mg should not be used in patients with glomerular filtration rate of less than 30 ml/minute.

Haemodialysis decreases serum concentrations of both amoxicillin and clavulanic acid and an additional dose should be administered at the end of dialysis.

Dosage Guide:

Amoxicillin-Sensitive Organisms

Product	Upper Respiratory Tract Infection	Lower Respiratory Tract Infection	Urinary Tract Infection	Skin and Soft Tissue Infection
AURO AMOXICLAV 375 mg	1 tablet 8 hourly	-	1 tablet 8 hourly	1 tablet 8 hourly
AURO AMOXICLAV 625 mg	1 tablet 8 hourly	1 tablet 8 hourly	1 tablet 8 hourly	1 tablet 8 hourly
AURO AMOXICLAV 1000 mg	1 tablet 12 hourly	1 tablet 12 hourly	1 tablet 12 hourly	1 tablet 12 hourly

Amoxicillin-Resistant Organisms

Product	Upper Respiratory Tract Infection	Lower Respiratory Tract Infection	Urinary Tract Infection	Skin and Soft Tissue Infection
AURO AMOXICLAV 375 mg	-	-	1 tablet 8 hourly	1 tablet 8 hourly
AURO AMOXICLAV 625 mg	1 tablet 8 hourly	1 tablet 8 hourly	1 tablet 8 hourly	1 tablet 8 hourly
AURO AMOXICLAV 1000 mg	1 tablet 12 hourly	1 tablet 12 hourly	1 tablet 12 hourly	1 tablet 12 hourly

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.

If you take more AURO AMOXICLAV than you should:
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.

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

5. POSSIBLE SIDE EFFECTS

AURO AMOXICLAV can have side effects.
The most frequently reported adverse effects are diarrhoea, nausea, vomiting, indigestion, abdominal pain, skin rashes, urticaria and erythema multiforme, vaginitis, abnormal taste, headache, dizziness, tiredness and hot flushes.

The incidence and severity of adverse effects, particularly nausea and diarrhoea, increased 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:**

Hypersensitivity reactions:
Skin rashes, pruritus and urticaria, serum sickness-like syndrome, erythema multiforme, rare cases of Stevens-Johnson syndrome, hypersensitivity vasculitis and less frequently bullous exfoliative dermatitis 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.
Interstitial nephritis can occur rarely.

Gastrointestinal reactions:
Nausea, vomiting, diarrhoea, gastritis, stomatitis, glossitis, black 'hairy' tongue, enterocolitis, mucocutaneous candidiasis and antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis). If gastrointestinal reactions are evident, they may be reduced by taking **AURO AMOXICLAV** at the start of a meal.

Hepatic effects:
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.**

Renal effects:
Crystalluria has been reported

Haematological effects:
Haemolytic anaemia, reversible thrombocytopenia, thrombocytopenic purpura, eosinophilia, reversible leucopenia and agranulocytosis 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.

Central Nervous System (CNS) effects:
CNS effects have been seen rarely. These include reversible hyperactivity, dizziness, headache and convulsions. Convulsions may occur with impaired renal function or in those receiving high doses.

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 this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

6. STORING AND DISPOSING OF AURO AMOXICLAV

Store all medicines out of the reach of children.
Store at or below 30 °C.

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 375 mg:
Tablets are packed in 25 micron polyamide /45 micron aluminium foil / 60 micron PVC film as the forming material and 25 micron printed aluminium foil as the lidding material.
Each blister contains 5 tablets.
Pack size: 15s: Each carton contains 3 blisters of 5 tablets each.
Pack size: 100s: Each carton contains 20 blisters of 5 tablets each.

AURO AMOXICLAV 625 mg:
Tablets are packed in 25 micron polyamide /45 micron aluminium foil / 60 micron PVC film as the forming material and 25 micron printed aluminium foil as the lidding material.
Each blister contains 5 tablets.
Pack size: 15s: Each carton contains 3 blisters of 5 tablets each.

AURO AMOXICLAV 1000 mg:
1. Tablets are packed in 25 micron polyamide / 45 micron aluminium foil / 60 micron PVC film as the forming material and 25 micron printed aluminium foil as the lidding material.
   Each blister contains 5 tablets.
   Pack size: 10s: Each carton contains 2 blisters of 5 tablets each.
2. Tablets are packed in printed 40 micron aluminium foil laminated with 150-gauge poly on one side and plain 40 micron aluminium foil laminated with 150-gauge poly on other side. Each strip contains 10 tablets.
   Pack size: 10s: One strip pack containing 10 tablets.

8. IDENTIFICATION OF AURO AMOXICLAV

AURO AMOXICLAV 375 mg:
White oval shaped film-coated tablets, debossed with 'A' on one side and '63' on the other side

AURO AMOXICLAV 625 mg:
White oval shaped film-coated tablets, debossed with 'A' on one side and '64' on the other side.

AURO AMOXICLAV 1000 mg:
White coloured, capsule shaped, film-coated tablets, debossed with 'A' on one side and with a score line in between '6' and '5' on the other side.

9. REGISTRATION NUMBER:

SOUTH AFRICA
AURO AMOXICLAV 375 mg: 41/20.1.2/0535
AURO AMOXICLAV 625 mg: 41/20.1.2/0536
AURO AMOXICLAV 1 000 mg: 41/20.1.2/0537

NAMIBIA
AURO AMOXICLAV 375 mg: 10/20.1.2/0250
AURO AMOXICLAV 625 mg: 10/20.1.2/0251
AURO AMOXICLAV 1 000 mg: 10/20.1.2/0252

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
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 OF THE PACKAGE INSERT:
Date of registration:
15 August 2008
Date of revision:
27 February 2022