BIO-AMOKSIKLAV 375

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM
BIO-AMOKSIKLAV 375. Each tablet contains amoxicillin trihydrate equivalent to 250 mg amoxicillin and potassium clavulanate equivalent to 125 mg clavulanic acid.

Read all of this leaflet carefully before you start taking BIO-AMOKSIKLAV 375
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- BIO-AMOKSIKLAV 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 BIO-AMOKSIKLAV CONTAINS
BIO-AMOKSIKLAV 375: Each film-coated tablet contains amoxicillin trihydrate equivalent to amoxicillin 250 mg and clavulanate potassium equivalent to clavulanic acid 125 mg as the active ingredients.
The other ingredients are: Colloidal anhydrous silica, croscarmellose sodium, crospovidone, ethylcellulose, hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, polysorbate 80, talc, titanium dioxide and triethyl citrate.
Sugar free.

2. WHAT BIO-AMOKSIKLAV IS USED FOR
BIO-AMOKSIKLAV can be used for infections that are resistant to amoxicillin, when the beta-lactamases (enzymes produced by the bacteria) are clavulanic acid sensitive.
BIO-AMOKSIKLAV can thus be used for the treatment of:
- upper respiratory tract infections (including sinusitis)
- recurrent middle-ear infections,
- tonsillitis
- lower respiratory tract infections, such as bronchitis and bronchopneumonia
- genito-urinary tract infections, such as cystitis, urethritis, pyelonephritis
- skin and soft tissue infections.

3. BEFORE YOU TAKE BIO-AMOKSIKLAV
Do not take BIO-AMOKSIKLAV:
- if you are hypersensitive (allergic) to penicillins, cephalosporins, cephamycins, or beta-lactamase inhibitors or any of the other ingredients of BIO-AMOKSIKLAV.
- if you have previously had jaundice or liver problems, after taking antibiotics containing amoxicillin / clavulanic acid.

Take special care with BIO-AMOKSIKLAV:
- if you have impaired liver or kidney function
- if you have infectious mononucleosis
- if you have a history of hypersensitivity reactions to penicillins, cephalosporins or other allergens. Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral penicillins.
- if you take allopurinol, as it can increase your risk of an allergic skin reaction
- if, at the start of treatment, you develop a fever and a rash, it may be a symptom of Acute Generalised Exanthemous Pustulosis (refer to "SIDE EFFECTS")
- if you are on prolonged treatment with BIO-AMOKSIKLAV, as it may result in an over growth of non-susceptible organisms
- if you suffer of severe diarrhoea, during or after using BIO-AMOKSIKLAV, as it may be a symptom of antibiotic-associated colitis. It can range in severity from mild, to life threatening. If your doctor diagnoses you with this condition, treatment with BIO-AMOKSIKLAV should be stopped, and appropriate treatment initiated. You must avoid anti-peristaltic medicines in this situation
- if you take anti-coagulation (anti-blood clotting) medicine (see "Using other medicines with BIO-AMOKSIKLAV" below)
- if you are on prolonged therapy with BIO-AMOKSIKLAV, your doctor should do periodic assessment of your organ functions
- if you have syphilis, as the Jarisch-Herxheimer reaction may occur
- you must maintain adequate fluid intake, especially if you are on prolonged treatment with BIO-AMOKSIKLAV
- if you are on a low-sodium diet, you should take the sodium content of BIO-AMOKSIKLAV into consideration if you are on a high dosage regimen
- The use of BIO-AMOKSIKLAV may lead to the selection of resistant strains of organisms, and sensitivity testing should, whenever possible, be done to demonstrate appropriateness of therapy
- if you are using an oral contraceptive (the Pill), as BIO-AMOKSIKLAV may reduce the efficacy of your oral contraceptive.

Taking BIO-AMOKSIKLAV with food and drink:
These tablets should be taken with food.
The most common side-effects are nausea, vomiting and diarrhoea. Taking the medicine with food can reduce these gastrointestinal symptoms.

Pregnancy and Breastfeeding:
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.
The safety of BIO-AMOKSIKLAV during pregnancy has not been established.
Amoxicillin, an active ingredient of BIO-AMOKSIKLAV, is excreted in breast milk, it may lead to the infant experiencing side effects of BIO-AMOKSIKLAV. Caution should be exercised when a breastfeeding woman uses BIO-AMOKSIKLAV.

Driving and using machinery:
Side effects such as allergic reactions, dizziness and convulsions may occur, which can influence your ability to drive and use machines. You should make sure how BIO-AMOKSIKLAV affects you, before driving and using machines.

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

The following medication may interact with BIO-AMOKSIKLAV and therefore you should notify your doctor or healthcare professional if you are taking medicines that contains any of the following before taking BIO-AMOKSIKLAV:
- probenecid (anti-gout medication), the simultaneous use with BIO-AMOKSIKLAV is not recommended
- tetracyclines and other bacteriostatic medicines, as it may interfere with the efficacy of BIO-AMOKSIKLAV
- allopurinol (anti-gout medication), as well as ampicillin, as it may increase your risk of an allergic skin reaction
- oral contraceptives (the Pill), (refer to "Take special care with BIO-AMOKSIKLAV" section) above
- warfarin, coumarin or any other anti-clotting medicines
- methotrexate, as BIO-AMOKSIKLAV can increase the toxicity of methotrexate
- mycophenolate mofetil, your dosage of mycophenolate mofetil may need to be adjusted.

Interaction of BIO-AMOKSIKLAV with laboratory tests:
BIO-AMOKSIKLAV may interfere with the results of the following laboratory tests:
- tests for glucose in the urine
- Coombs test
- Aspergillus EIA tests.

4. HOW TO TAKE BIO-AMOKSIKLAV TABLETS
Do not share medicines prescribed for you with any other person.
BIO-AMOKSIKLAV 375: 1 or 2 tablets must be taken every eight hours.
Always take BIO-AMOKSIKLAV exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
If you suffer from kidney problems, your doctor may adjust or reduce the dosage.
Your doctor will tell you how long your treatment will last, do not stop treatment early. You must complete your course of BIO-AMOKSIKLAV. If you have the impression that the effect of BIO-AMOKSIKLAV is too strong or too weak, tell your doctor or pharmacist.

If you take more BIO-AMOKSIKLAV than you should
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 BIO-AMOKSIKLAV
If you miss a dose do not worry, take it as soon as you remember. Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS
BIO-AMOKSIKLAV can have side effects. Not all side effects reported for BIO-AMOKSIKLAV are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIO-AMOKSIKLAV, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking BIO-AMOKSIKLAV and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- swollen lymph nodes
- hives, rash or severe itching
- fainting, fever, joint pain
- yellowing of the skin and eyes (also called jaundice)
- Stevens-Johnson syndrome, bullous exfoliative dermatitis and toxic epidermal necrolysis, characterised by a red or purple rash that spreads within hours to days, blistering of the skin, mouth, eyes and genitals
- Acute Generalised Exanthemous Pustulosis (AGEP), a condition characterised by fever and multiple small pustules (pimple-like rash).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BIO-AMOKSIKLAV. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
Frequent serious side effects are:
- persistent or recurrent superficial infections of the skin, mucous membranes and nails with Candida organisms (known as mucocutaneous candidiasis)
- antibiotic associated colitis (severe diarrhoea).

Less frequent serious side effects are:
- certain blood conditions characterised by pale skin, weakness, breathlessness, easy bruising, prolonged bleeding from cuts, bleeding from nose or gums, blood in urine or stools, reddish purple spots on skin
- convulsions (fits).

Serious side effects with unknown frequency are:
- interstitial nephritis, it is a condition characterised by blood in urine, increased or decreased urine output, fluid retention.

Tell your doctor if you notice any of the following:
Frequent side effects are:
- nausea, vomiting, diarrhoea, gastritis, indigestion, abdominal pain, inflammation of the mouth and tongue and black 'hairy' tongue
- tiredness
- hot flushes.

Less frequent side effects are:
- hyperactivity
- dizziness
- headache
- abnormal taste.

Side effects with unknown frequency are:
- cloudy urine.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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6. STORING AND DISPOSING OF BIO-AMOKSIKLAV
- Keep your tablets in the bottle or blister they came in. Do not put it in another container. Keep the bottle closed tightly and do not remove the desiccant.
- Store the tablets at or below 25 °C.
- Protect the tablets from moisture and light.
- Store all medicines out of reach of children.
- The EXPIRY date is marked on the bottle. Do not use the tablets past the expiry date.
- Return all unused medicines to your pharmacist.
- Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF BIO-AMOKSIKLAV
BIO-AMOKSIKLAV 375: Tablets are packed in either amber glass containers containing 15 tablets or aluminium blister strip containing 5 tablets. Three blister strips are packed in an outer carton.

8. IDENTIFICATION OF BIO-AMOKSIKLAV
BIO-AMOKSIKLAV 375: White to almost white, octagonal, biconvex film-coated tablets, debossed with 250/125 on one side and AMC on the other side.

9. REGISTRATION NUMBER
BIO-AMOKSIKLAV 375: 31/20.1.2/0681

10. NAME AND ADDRESS OF REGISTRATION HOLDER
Biotech Laboratories (Pty) Ltd.
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11. DATE OF PUBLICATION
Date of Registration:
BIO-AMOKSIKLAV 375: 23 August 1999
Date of latest revision of the text as approved by Council: 11 March 2010
Date of notification regarding amended Reg. 9 and 10: 06 February 2015

BIO-AMOKSIKLAV 375

PASIëNTINLIGTINGSBLAD

SKEDULERING STATUS

S4

HANDELSNAAM, STERKTE EN FARMASEUTIESE VORM
BIO-AMOKSIKLAV 375. Elke tablet bevat amoksisillientrihidraat gelykstaande aan 250 mg amoksisillien en kaliumklavulanaat gelykstaande aan 125 mg klavulaansuur.

Lees hierdie hele blad noukeurig deur voordat u begin om BIO-AMOKSIKLAV 375 te drink.
- Hou hierdie blad. Dit mag nodig wees dat u dit weer moet lees.
- As u nog enige vrae het, moet u asseblief vir u dokter, apteker of ander gesondheidspraktisyn vra.
- BIO-AMOKSIKLAV 375 is vir u persoonlik voorgeskryf en u moet nie u medisyne vir ander mense gee nie. Dit kan hulle skaad, selfs al is hulle simptome dieselfde as u s'n.

1. WAT BIO-AMOKSIKLAV BEVAT
BIO-AMOKSIKLAV 375: Elke filmbedekte tablet bevat amoksisillientrihidraat gelykstaande aan 250 mg amoksisillien en kaliumklavulanaat gelykstaande aan 125 mg klavulaansuur as aktiewe bestanddele.
Die ander bestanddele is: Kolloïdale watervrye silika, natrium kroskarmellose, krospovidoon, etielsellulose, hydroxypropyl sellulose, magnesiumstearaat, mikrokristallyne sellulose, polysorbaat 80, talk, titaandioksied en trietielsitraat.
Vry van suiker

2. WAARVOOR BIO-AMOKSIKLAV GEBRUIK WORD
BIO-AMOKSIKLAV kan gebruik word in infeksies wat bestand is teen amoksisillien, wanneer die beta-laktamases (ensieme wat deur die bakterieë vervaardig word) klavulansuursensitief is.
BIO-AMOKSIKLAV kan dus aangewend word vir die behandeling van:
- Boonste lugweginfeksies (insluitend sinusitis)
- Herhalende middeloorfinfeksies,
- tonsillitis
- lae lugweginfeksies, soos brongitis en bronchopneumonie
- genito-urinêre weg infeksies, soos sistitus, uretritis, piëlonefritis
- vel-en-sagteweefsel infeksies

3. VOORDAT U BIO-AMOKSIKLAV NEEM
Moet nie BIO-AMOKSIKLAV neem as:
- u hipersensitief (allergies) is vir penisilliene, kefalosporiene, kefamisiene, of beta-laktamase-remmers of enige van die ander bestanddele van BIO-AMOKSIKLAV.
- u voorheen geelsug gehad het of lewerprobleme het, nadat u antibiotika wat amoksisillien/klavulaansuur bevat geneem het

Wees besonder versigtig met BIO-AMOKSIKLAV indien:
- u ingeperkte lewer of nierfunksie het
- as u aansteeklike mononukleose het
- as u 'n geskiedenis van hipersensitiwiteitsreaksies vir penisilliene, kefalosporiene of ander allergene het. Alhoewel anafilakse meer gereeld voorkom na parenterale terapie, kom dit voor by pasiënte wat penisilliene gebruik
- as u allopurinol neem, aangesien dit die risiko van 'n allergiese velreaksie kan verhoog
- as u aan die begin van die behandeling koors en uitslag ontwikkel, kan dit 'n simptoom wees van akute veralgemeende eksantemiese pustulose (verwys na "NEWE-EFFEKTE")
- as u langdurige behandeling met BIO-AMOKSIKLAV ondergaan, aangesien dit kan lei tot oorgroei van nie-vatbare organismes
- as u aan ernstige diarree ly tydens of na die gebruik van BIO-AMOKSIKLAV, aangesien dit 'n simptoom kan wees van antibiotika-geassosieerde kolitis. Dit kan wissel van lig tot lewensgevaarlik. As u dokter u met hierdie toestand gediagnoseer het, moet die behandeling met BIO-AMOKSIKLAV gestaak word en moet gepaste behandeling begin word. In hierdie situasie moet u anti-peristaltiese medisyne vermy
- as u medisyne teen koagulasie (bloedstolling) gebruik (sien "Gebruik van ander medisyne saam met BIO-AMOKSIKLAV" hieronder)
- as u langdurige terapie met BIO-AMOKSIKLAV ondergaan, moet u dokter u orgaanfunksies gereeld evalueer
- as u sifilis het, aangesien die Jarisch-Herxheimer-reaksie kan voorkom
- u moet voldoende vloeistofinname handhaaf, veral as u langdurige behandeling met BIO-AMOKSIKLAV ondergaan
- as u 'n lae-natriumdieet volg, moet u die natriuminhoud van BIO-AMOKSIKLAV in ag neem as u 'n hoë dosis gebruik
- Die gebruik van BIO-AMOKSIKLAV kan lei tot die seleksie van weerstandbiedende organismestamme, en sensitiwiteitstoets moet, waar moontlik, gedoen word om die toepaslikheid van terapie aan te toon.
- as u 'n mondelinge voorbehoedmiddel (die pil) gebruik, aangesien BIO-AMOKSIKLAV die doeltreffendheid van u orale voorbehoedmiddel kan verminder.

Neem van BIO-AMOKSIKLAV met voedsel en drank:
Hierdie tablette moet saam met voedsel geneem word.
Die mees algemene newe-effekte is naarheid, braking en diaree. Deur die medisyne saam met voedsel te neem, kan die gastrointestinale simptome verminder word.

Swangerskap en Borsvoeding:
As u swanger is of u baba borsvoed, raadpleeg u dokter, apteker of enige ander gesondheidsorgpraktisyn vir raad voordat u hierdie medisyne neem.
Die veiligheid van BIO-AMOKSIKLAV gedurende swangerskap is nog nie vasgestel nie.
Amoksisillien, as aktiewe bestanddeel van BIO-AMOKSIKLAV, word wel in borsmelk uitgeskei, wat daartoe mag lei dat die baba newe-effekte van BIO-AMOKSIKLAV kan ervaar.
BIO-AMOKSIKLAV.moet versigtitg gebruik word in borsvoedende vroue.

Motorbestuur en gebruik van masjinerie:
Newe-effekte soos allergiese reaksies, duiseligheid en stuiptrekkings mag voorkom, wat u vermoë om te bestuur of masjinerie te gebruik, kan beïnvloed. U moet seker maak hoe BIO-AMOKSIKLAV u beïnvloed, voordat u bestuur en masjiene gebruik.

Ander medisyne en BIO-AMOKSIKLAV
Sê altyd vir u gesondheidsorgpraktisyn as u enige ander medisyne gebruik (waaronder alle aanvullende of tradisionele medisyne).

Die volgende medikasie kan interaksies met BIO-AMOKSIKLAV veroorsaak, en daarom moet u u dokter of gesondheidsorgpraktisyn inlig as u medisyne neem wat die volgende bevat, voordat u BIO-AMOKSICLAV begin gebruik:
- probenesied (anti-jig medikasie), die gelyktydige gebruik met BIO-AMOKSIKLAV word nie aanbeveel nie
- tetrasikliene en ander bakteriostatiese medisyne, aangesien dit die doeltreffendheid van BIO AMOKSIKLAV kan belemmer
- allopurinol (anti-jig medikasie), sowel as ampisillien, aangesien dit u risiko vir 'n allergiese velreaksie kan verhoog
- mondelinge voorbehoedmiddels (die pil), (verwys na die afdeling "Wees veral versigtig met BIO-AMOKSIKLAV")
- warfarien, kumarien of ander antistollingsmedisyne
- metotreksaat, aangesien BIO-AMOKSIKLAV die giftigheid van metotreksaat kan verhoog
- mycophenolate mofetil, u dosis van mycophenolate mofetil moet moontlik aangepas word.

Interaksie van BIO-AMOKSIKLAV met laboratorium toetse:
BIO-AMOKSIKLAV kan inmeng met die resultate van die volgende laboratorium toetse:
- toets vir glukose in die uriene
- Coombs toets
- Aspergillus EIA toets

4. HOE OM BIO-AMOKSIKLAV TABLETTE TE NEEM
Moenie medisyne wat vir u voorgeskryf is vir enige ander persoon gee nie.
BIO-AMOKSIKLAV 375: 1 of 2 tablette moet elke agt ure geneem word.
Gebruik BIO-AMOKSIKLAV altyd presies soos wat u dokter of apteker vir u gesê het. Raadpleeg u dokter of apteker as u nie seker is nie.
As u nierprobleme het, kan u dokter moontlike u dosering aanpas.
U dokter sal u inlig oor hoe lank die behandeling met BIO-AMOKSIKLAV sal duur, moet nie behandeling vroeg staak nie. U moet u kursus van BIO-AMOKSIKLAV voltooi. Sê vir u dokter of apteker as u die indruk het dat die effek van BIO-AMOKSIKLAV te sterk of te swak is.

Indien u meer BIO-AMOKSIKLAV gedrink het as wat u moes
In die geval van oordosering, raadpleeg u dokter of apteker. Indien beide nie beskikbaar is nie, gaan na die naaste hospitaal of gifbeheersentrum.

As us vergeet om BIO-AMOKSIKLAV te neem
As u 'n dosis mis, moet nie bekommer nie, neem dit so gou as wat u onthou. Moet nie 'n dubbele dosis neem om op te maak vir 'n vergete dosis nie.

5. MOONTLIKE NEWE-EFFEKTE
BIO-AMOKSIKLAV kan newe-effekte veroorsaak. Nie alle newe-effekte wat al aangemeld is vir BIO-AMOKSICLAV is ingesluit in hierdie blad nie. Indien u algemene gesondheid verswak of as u ongewone effekte ervaar terwyl u BIO-AMOKSIKLAV neem, raadpleeg u dokter, apteker of enige ander gesondheidsorgpraktisyn vir advies.

As enige van die volgende newe-effekte voorkom, staak behandeling met BIO-AMOKSICLAV en lig dadelik u dokter in of gaan so gou moontlik na die ongevalle afdeling by u naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe , mond of keel, wat asemhaling of sluk belemmer
- Geswelde limfkliere
- Knoppe, uitslag of erge gejeuk
- Floute, koors, gewrigspyn
- vergeling van die vel en oë (ook geelsug genoem)
- Stevens-Johnson-sindroom, bulleuse eksfoliatiewe dermatitis en toksiese epidermale nekrolise, gekenmerk deur 'n rooi of pers uitslag wat binne enkele dae versprei, blase op die vel, mond, oë en geslagsdele
- Akute algemene eksantemiese pustulose (AGEP), 'n toestand wat gekenmerk word deur koors en veelvuldige klein pusteles (puisie-agtige uitslag).

Hierdie is almal ernstige newe-effekte. As u dit ondervind, dui dit op 'n ernstige allergiese reaksie teenoor BIO-AMOKSIKLAV. U mag mediese aandag of hospitalisasie benodig.

Lig u dokter onmiddellik in of gaan na die ongevalle afdeling van u naaste hospitaal as u enige van die volgende opmerk:
Algemene ernstige newe-effekte is:
- Aanhoudende of herhalende oppervlakkige vel- infeksies, mukus membrane en naels met Candida organismes (bekend as mukokutane candidiase)
- antibiotika -geassosieerde kolitis (erge diarree).

Minder algemene ernstige newe-effekte is:
- sekere bloedtoestande wat gekenmerk word deur bleek vel, swakheid, asemloosheid, maklike kneusing, langdurige bloeding deur snye, bloeding van neus of tandvleis, bloed in urine of ontlasting, rooi pers kolle op die vel
- stuiptrekkrings (aanvalle).

Ernstige newe-effekte met onbekende voorkoms:
- interstisiële nefritis, 'n toestand wat gekenmerk word deur bloed in die urine, verhoogde of verminderde urienuitset, vloeistofretensie..

Lig u dokter in as u enige van die volgende opmerk:
Algemene newe-effekte is:
- naarheid, braking, diarree, gastritis, spysvertering, buikpyn, ontsteking van die mond en tong en swart 'harige' tong
- moegheid
- warm gloede

Minder algemene newe-effekte is:
- hiperaktiwiteit
- duiseligheid
- hoofpyn
- abnormale smaak sensasie

Newe-effekte met minder bekende voorkoms is:
- troebel uriene

As u enige newe -effekte opmerk wat nie in hierdie pamflet genoem word nie, moet u u dokter of apteker daarvan in kennis stel.

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6. BERGING EN VERNIETIGING VAN BIO-AMOKSIKLAV
- Bewaar u tablette in die bottle of stulpstrook waarin u dit gekry het. Moet dit nie in 'n ander houer plaas nie. Hou die bottle dig toe en moet die nie droogmiddel verwyder nie.
- Bewaar teen of benede 25 °C.
- Beskerm die tablette teen vog en lig.
- Bewaar alle medisyne buite die bereik van kinders.
- Die VERVALDATUM is aangedui op die bottle. Moet nie die tablette gebruik na die vervaldatum nie.
- Oorhandig alle ongebruikte medisyne aan u apteker.
- Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. Toilette) weggooi nie.

7. AANBIEDING VAN BIO-AMOKSIKLAV
BIO-AMOKSIKLAV 375: Die tablette word verpak in amberglashouers met 15 tablette of aluminiumblister-stroke met 5 tablette. Drie blisterstroke word in 'n buitenste karton verpak.

8. IDENTIFIKASIE VAN BIO-AMOKSIKLAV
BIO-AMOKSIKLAV 375:
Wit tot byna wit, agtkantige, bikonvekse film-omhulde tablette, met 250/125 aan die een kant en AMC aan die ander kant.

9. REGISTRASIE NOMMER
BIO-AMOKSIKLAV 375: 31/20.1.2/0681

10. NAAM EN ADRES VAN DIE HOUER VAN DIE REGISTRASIE SERTIFIKAAT
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11. DATUM VAN PUBLIKASIE
Date of Registration:
BIO-AMOKSIKLAV 375: 23 August 1999
Datum van die laaste hersiening van die teks soos goedgekeur deur die Raad: 11 Maart 2010
Datum van kennisgewing aangaande gewysigde Reg. 9 en 10: 06 Februarie 2015