NEW ZEALAND DATA SHEET

1. PRODUCT NAME

AMOXICLAV Devatis Duo 400 mg/57 mg/5 ml Powder for Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Drug Substance:
The active substances are amoxicillin and clavulanic acid.
When reconstituted, 5 ml of suspension contain amoxicillin trihydrate equivalent to 400 mg amoxicillin and potassium clavulanate equivalent to 57 mg of clavulanic acid.

Excipients:
For full list of excipients see 6.1.

3. PHARMACEUTICAL FORM

Powder for oral suspension.
White to creamy white powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

AMOXICLAV Devatis Duo should be used in accordance with local official antibiotic prescribing guidelines and local susceptibility data.

AMOXICLAV Devatis Duo is indicated for the short term treatment of common bacterial infections in adults and children such as:

- **Upper Respiratory Tract Infections (including ENT):** e.g. tonsillitis, sinusitis, otitis media
- **Lower Respiratory Tract Infections:** e.g. acute exacerbations of chronic bronchitis, lobar and broncho-pneumonia
- **Genito-urinary Tract Infections:** e.g. cystitis, urethritis, pyelonephritis, female genital infections
- **Skin and Soft Tissue Infections**
- **Bone and Joint Infections:** e.g. osteomyelitis
- **Other Infections:** e.g. septic abortion, puerperal sepsis, intra-abdominal sepsis, septicaemia, peritonitis, post-surgical infections

Susceptibility to AMOXICLAV Devatis Duo will vary with geography and time. Local susceptibility data should be consulted where available, and microbiological sampling and susceptibility testing performed where necessary.
Infections caused by amoxicillin susceptible organisms are amenable to AMOXICLAV Devatis Duo treatment due to its amoxicillin content. Mixed infections caused by amoxicillin susceptible organism in conjunction with AMOXICLAV Devatis Duo-susceptible beta-lactamase- producing organisms may therefore be treated by AMOXICLAV Devatis Duo.

4.2 Dose and method of administration

Dose
Children 7-12 years: 5 ml of AMOXICLAV Devatis Forte 3 times daily. In severe infections this may be increased to 10 ml of AMOXICLAV Devatis Forte 3 times a day.

Children 2-6 years: 2.5 ml of AMOXICLAV Devatis Forte 3 times a day. In severe infections this may be increased to 5 ml AMOXICLAV Devatis Forte 3 times a day.

Children 9 months - 2 years: 1.25 ml of AMOXICLAV Devatis Forte 3 times a day.

Children 3 - 9 months: 0.625 ml of AMOXICLAV Devatis Forte 3 times a day.

Premature: No dosage recommendations can be made for this category.

Special populations

Elderly
No adjustment needed, dose as for adults. If there is evidence of renal impairment, dose should be adjusted as for renally impaired adults (see below).

Renal impairment
Children: Dosing adjustments are based on the maximum recommended level of amoxicillin.

	Mild Impairment (creatinine clearance >30 ml/min)	Moderate Impairment (creatinine clearance 10-30 ml/min)	Severe Impairment (creatinine clearance <10 ml/min)
Oral Solution (in the majority of cases, parenteral therapy, where available, may be preferred).	No change in dosage	15/3.75 mg/kg given 12 hourly (maximum 500/125 mg twice daily).	15/3.75 mg/kg given as a single daily dose (maximum 500/125 mg). Dialysis decreases serum concentrations of AMOXICLAV Devatis Duo. Prior to hemodialysis one additional dose of 15/3.75 mg/kg should be administered. In order to restore circulating drug levels, another dose of 15/3.75 mg/kg should be administered after hemodialysis.

Hepatic impairment
Dose with caution; monitor hepatic function at regular intervals for both adults and children.
There are as yet insufficient data on which to base a dosage recommendation.

Method of administration
To minimize potential gastrointestinal intolerance, administer at the start of a meal.

The absorption of AMOXICLAV Devatis Duo is optimized when taken at the start of a meal.

Treatment should not be extended beyond 14 days without review.

Therapy can be started parenterally and continued with an oral preparation.

For administration of suspensions to children below 3 months, a syringe graduated to permit accurate and reproducible volumes to be dispensed, should be used.

For administration to children up to 2 years old, AMOXICLAV Devatis Duo suspensions may be diluted to half-strength using water.

Shake well before taking each dose.

For instructions on reconstitution of the medicine before administration, see section 6.6 Special precautions for disposal and other handling.

4.3 Contraindications

In patients with a history of hypersensitivity to beta-lactams, e.g. penicillins and cephalosporins.

AMOXICLAV Devatis Duo is contraindicated in patients with a previous history of AMOXICLAV Devatis Duo -associated jaundice/hepatic dysfunction.

4.4 Special warnings and precautions for use

Before initiating therapy with AMOXICLAV Devatis Duo, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalolosporins or other allergens.

Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity (see section 4.3 Contraindications). Hypersensitivity reactions can also progress to Kounis syndrome, a serious allergic reaction that can result in myocardial infarction. Presenting symptoms of such reactions can include chest pain occurring in association with an allergic reaction to AMOXICLAV (see section 4.8 Undesirable effects). Drug-induced enterocolitis syndrome has been reported mainly in children receiving amoxicillin-clavulanate (see section 4.8 Undesirable effects). Drug-induced enterocolitis syndrome is an allergic reaction with the leading symptom of protracted vomiting (1-4 hours after medicinal product administration) in the absence of allergic skin or respiratory symptoms. Further symptoms could comprise abdominal pain, lethargy, diarrhoea, hypotension or leucocytosis with neutrophilia. In severe cases, drug-induced enterocolitis syndrome can progress to shock. If an allergic reaction occurs, AMOXICLAV Devatis Duo therapy should be discontinued and appropriate alternative therapy instituted. Serious anaphylactic reactions require immediate emergency treatment with adrenaline. Oxygen, intravenous steroids and airway management, including intubation may also be required.

AMOXICLAV Devatis Duo therapy should be avoided if infectious mononucleosis is suspected since the occurrence of a morbilliform rash has been associated with this condition following the use of amoxicillin.

Prolonged use may also occasionally result in overgrowth of non-susceptible organisms.

Pseudomembranous colitis has been reported with the use of antibiotics and may range in severity from mild to life threatening. Therefore, it is important to consider its diagnosis in patients who develop diarrhoea during or after antibiotic use. If prolonged or significant diarrhoea occurs or the patient experiences abdominal cramps, treatment should be discontinued immediately and the patient investigated further.

In general AMOXICLAV Devatis Duo is well tolerated and possesses the characteristic low toxicity of the penicillin group of antibiotics. Periodic assessment of organ system functions, including renal, hepatic and hematopoietic function is advisable during prolonged therapy.

Abnormal prolongation of prothrombin time (increase in INR value) has been reported rarely in some patients receiving AMOXICLAV Devatis Duo and oral anticoagulants. Appropriate monitoring should be undertaken when anticoagulants are prescribed concurrently. Adjustments in the dose of oral anticoagulants may be necessary to maintain the desired level of anticoagulation.

AMOXICLAV Devatis Duo should be used with caution in patients with evidence of hepatic dysfunction. Hepatic events have been reported predominantly in males and elderly patients and may be associated with prolonged treatment. These events have been very rarely reported in children.

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. These are usually reversible. Hepatic events may be severe and in extremely rare circumstances, deaths have been reported. These have almost always occurred in patients with serious underlying disease or taking concomitant medications known to have the potential for hepatic effects.

In patients with renal impairment, dosage should be adjusted according to the degree of impairment (see section 4.2).
Convulsions may occur in patients with impaired renal function or in those receiving high doses.

The occurrence at treatment initiation of a feverish generalized erythema associated with pustule may be a symptom of acute generalized exanthemous pustulosis (AEGP). This reaction requires AMOXICLAV Devatis Duo discontinuation and is a contraindication to subsequent administration of amoxicillin.

The presence of clavulanic acid may cause a non-specific binding of IgG and albumin by red cell membranes leading to a false positive Coombs test.

In patients with reduced urine output, crystalluria has been observed very rarely, predominantly with parenteral therapy. During the administration of high doses of amoxicillin, it is advisable to maintain adequate fluid intake and urinary output in order to reduce the possibility of amoxicillin crystalluria (see section 4.9).

4.5 Interaction with other medicinal products and other forms of interaction

Probenecid:
Concomitant use of probenecid is not recommended. Probenecid decreases the renal tubular secretion of amoxicillin. Concomitant use of probenecid with AMOXICLAV Devatis Duo may result in increased and prolonged blood levels of amoxicillin, but not of clavulanic acid.

Allopurinol:
Concomitant use of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reactions. No data is available regarding the concomitant use of allopurinol and AMOXICLAV Devatis Duo.

Oral contraceptives:
As with other antibiotics, AMOXICLAV Devatis Duo may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives.

Oral anticoagulants:
In the literature there are cases of increased international normalised ratio in patients maintained on acenocoumarol or warfarin and prescribed a course of amoxicillin. If co-administration is necessary, the prothrombin time or international normalised ratio should be carefully monitored with the addition or withdrawal of amoxicillin.

Mycophenolate mofetil
In patients receiving mycophenolate mofetil, reduction in pre-dose concentration of the active metabolite mycophenolic acid of approximately 50% has been reported following commencement of oral amoxicillin plus clavulanic acid. The change in pre-dose level may not accurately represent changes in overall MPA exposure.

Methotrexate
Penicillins may reduce the excretion of methotrexate causing a potential increase in toxicity.

4.6 Fertility, pregnancy and lactation

Pregnancy
Reproduction studies in animals (mice and rats at doses up to 10 times the human dose) with orally and parentally administered amoxicillin/clavulanic acid, have shown no teratogenic effects. In a single study in women with preterm, premature rupture of the foetal membrane (pPROM), it was reported that prophylactic treatment with amoxicillin/clavulanic acid may be associated with an increased risk of necrotizing enterocolitis in neonates. As with all medicines, use should be avoided in pregnancy, unless considered essential by the physician.

Breast-feeding
AMOXICLAV Devatis Duo may be administered during the period of lactation. With the exception of the risk of sensitization, associated with the excretion of trace quantities in breast milk, there are no known detrimental effects for the breastfed infant.

Fertility
There are no data on the effects of amoxicillin trihydrate/potassium clavulanate on fertility in humans.

4.7 Effects on ability to drive and use machines
Adverse effects on the ability to drive or operate machinery have not been observed.

4.8 Undesirable effects

Tabulated list of adverse reactions
Data from large clinical trials was used to determine the frequency of very common to rare undesirable effects. The frequencies assigned to all other undesirable effects (i.e., those occurring at <1/10,000) were mainly determined using post-marketing data and refer to a reporting rate rather than a true frequency.

Classification of frequency is as follows:
Very common ≥1/10
Common ≥1/100 to <1/10
Uncommon ≥1.000 to <1/100
Rare ≥1/10.000 to <1/1.000
Very rare <1/10.000

Infections and infestations	
Common	Mucocutaneous candidiasis
Blood and lymphatic system disorders	
Rare	Reversible leucopoenia (including neutropenia) and thrombocytopenia
Very rare:	Reversible agranulocytosis and haemolytic anaemia. Prolongation of bleeding and prothrombin time
Immunity system disorders	
Very rare:	Angioneurotic oedema, anaphylaxis (see section 4.4 Special Warnings and Precautions), serum sickness-like syndrome, hypersensitivity vasculitis (see also Skin and subcutaneous tissue disorders).
Nervous system disorders	
Uncommon	Dizziness, headache
Very rare:	Aseptic meningitis, reversible hyperactivity and convulsions. Convulsions may occur in patients with impaired renal function or receiving high doses.
Cardiac disorders	
Very rare	Kounis syndrome (see section 4.4 Special warnings and precautions for use)
Gastrointestinal disorders following oral administration to adults	
Very	Diarrhoea

common	
Common	Nausea, vomiting
Uncommon	Indigestion
Very Rare	Antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis) (see section 4.4 Special warnings and precautions for use). Black hairy tongue. Superficial tooth discolouration has been reported very rarely in children. Good oral hygiene may help to prevent tooth discolouration as it can usually be removed by brushing.
Gastrointestinal disorders following oral administration to paediatrics	
Common	Diarrhoea, nausea, vomiting Nausea is more often associated with high oral doses. If gastrointestinal reactions are evident, they may be reduced by taking AMOXICLAV Devatis Duo at the start of a meal.
Uncommon	Indigestion
Very rare:	Antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis), drug-induced enterocolitis syndrome (see section 4.4 Special warnings and precautions for use). Black hairy tongue. Superficial tooth discoloration has been reported very rarely in children. Good oral hygiene may help to prevent tooth discoloration as it can usually be removed by brushing.
Hepatobiliary disorders	
Uncommon	A moderate rise in AST and/or ALT are noted in patients treated with beta-lactam class antibiotics, but the significance of these findings is unknown.
Very rare:	Hepatitis and cholestatic jaundice. These events have also been noted with other penicillins and cephalosporins (see section 4.4 Special warnings and precautions for use).
Skin and subcutaneous tissue disorders	
Uncommon	Skin rash, pruritus, urticaria
Rare	Erythema multiforme
Very rare:	Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous exfoliative-dermatitis, acute generalised exanthemous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS) and symmetrical drug-related intertriginous and flexanthema (SDRIFE) (baboon syndrome) (see also Immune system disorders). If any hypersensitivity dermatitis reaction occurs, treatment should be discontinued. Linear IgA disease.
Renal and urinary disorders	
Very rare:	Interstitial nephritis, crystalluria (see section 4.9).

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions via: https://nzphvc.otago.ac.nz/reporting.

4.9 Overdose

Gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident. They may be treated symptomatically, with attention to the water/electrolyte balance.

Amoxicillin crystalluria, in some cases leading to renal failure, has been observed (see section 4.4).

When present at high concentrations in urine at room temperature, amoxicillin may precipitate in bladder catheters. A regular check of potency should be maintained.

AMOXICLAV Devatis Duo can be removed from the circulation by hemodialysis.

A prospective study of 51 paediatric patients at a poison control centre suggested that overdosages of less than 250 mg/kg of amoxicillin are not associated with significant clinical symptoms and do not require gastric emptying.

Drug abuse and dependence: Drug dependency, addiction and recreational abuse have not been reported as a problem with this compound.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Combinations of penicillins, including beta-lactamase inhibitors
ATC code: J01CR02

Mechanism of action:
AMOXICLAV Devatis Duo (beta-lactam antibacterial penicillin co-formulated with a beta-lactamase inhibitor) is an antibiotic agent with a notably broad spectrum of activity against the commonly occurring bacterial pathogens in general practice and hospital. The beta-lactamase inhibitory action of clavulanate extends the spectrum of amoxicillin to embrace a wider range of organisms, including many resistant to other beta-lactam antibiotics.
Amoxicillin is a semisynthetic antibiotic with a broad spectrum of antibacterial activity against many gram-positive and gram-negative micro-organisms. Amoxicillin is, however susceptible to degradation by beta-lactamases and therefore the spectrum of activity of amoxicillin alone does not include organisms which produce these enzymes.
Clavulanic acid is a beta-lactam, structurally related to the penicillins, which possesses the ability to inactivate a wide range of beta-lactamase enzymes commonly found in micro-organisms resistant to penicillins and cephalosporins. In particular, it has good activity against the clinically important plasmid mediated beta-lactamases frequently responsible for transferred drug resistance. It is generally less effective against chromosomally-mediated type 1 beta-lactamases.
The presence of clavulanic acid in AMOXICLAV Devatis Duo formulations protects amoxicillin from degradation by beta-lactamase enzymes and effectively extends the antibacterial spectrum of amoxicillin to include many bacteria normally resistant to amoxicillin and other penicillins and cephalosporins. Thus AMOXICLAV Devatis Duo possesses the distinctive properties of a broad spectrum antibiotic and a beta-lactamase inhibitor.

Pharmacodynamic effects:
In the list below, organisms are categorized according to their in vitro susceptibility to amoxicillin-clavulanate.

In vitro susceptibility of micro-organisms to amoxicillin-clavulanate Where clinical efficacy of amoxicillin-clavulanate has been demonstrated in clinical studies, this is indicated with an asterisk (*). Organisms that do not produce beta-lactamase are defined with (†). If an isolate is susceptible to amoxicillin, it can be considered to be also susceptible to amoxicillin/clavulanate
Commonly susceptible species
Gram-positive aerobes: *Bacillus anthracis* *Enterococcus faecalis* *Listeria monocytogenes*

Nocardia asteroides
Streptococcus pyogenes†*
Streptococcus agalactiae†*
*Streptococcus spp. (other β-hemolytic) *†*
*Staphylococcus aureus (methicillin susceptible)**
Staphylococcus saprophyticus (methicillin susceptible)
Coagulase negative staphylococcus (methicillin susceptible)

Gram-negative aerobes:
Bordetella pertussis
*Haemophilus influenzae**
Haemophilus parainfluenzae
Helicobacter pylori
*Moraxella catarrhalis**
Neisseria gonorrhoeae
Pasteurella multocida
Vibrio cholera

Other
Borrelia burgdorferi
Leptospira ictterohaemorrhagiae
Treponema pallidum

Gram positive anaerobes:
Clostridium species
Peptococcus niger
Peptostreptococcus magnus
Peptostreptococcus micros
Peptostreptococcus spp.

Gram-negative anaerobes:
Bacterodies fragilis
Bacteroides spp.
Capnocytophaga spp.
Eikenella corrodens
Fusobacterium nucleatum
Fusobacterium spp.
Porphyromonas spp.
Prevotella spp.

Species for which acquired resistance may be a problem

Gram-negative aerobes:
*Escherichia coli**
Klebsiella oxytoca
*Klebsiella pneumoniae**
Klebsiella spp.
Proteus mirabilis
Proteus vulgaris
Proteus spp.
Salmonella spp.
Shigella spp.

Gram-positive aerobes:

Corynebacterium spp. *Enterococcus faecium* *Streptococcus pneumoniae*†* *Viridans group streptococcus*
Inherently resistant organisms
Gram-negative aerobes: *Acinetobacter spp.* *Citrobacter freundii* *Enterobacter spp.* *Hafnia alvei* *Legionella pneumophila* *Morganella morganii* *Providencia spp.* *Pseudomonas spp.* *Serratia spp.* *Stenotrophomas maltophilia* *Yersinia enterolitica* Others *Chlamydia pneumoniae* *Chlamydia psittaci* *Chlamydia spp.* *Coxiella burnetii* *Mycoplasma spp.*

5.2 Pharmacokinetic properties

Absorption:
The two components of AMOXICLAV Devatis Duo, amoxicillin and clavulanic acid are fully dissociated in aqueous solution at physiological pH. Both components are rapidly and well absorbed by the oral route of administration. Absorption of AMOXICLAV Devatis Duo is optimized when taken at the start of a meal.

The pharmacokinetic results for two separate studies, in which Amoxicillin/Clavulanic 500/125 (625 mg) tablets (in comparison with the two components given separately) were administered in the fasting state to groups of healthy volunteers, are presented below.

Mean Pharmacokinetic Parameters					
Drug Administration	**Dose (mg)**	**C_{max} (µg/ml)**	**T_{max}* (h)**	**AUC $_{(0-24h)}$ (µg.h/ml)**	**$T_{1/2}$ (h)**
Amoxicillin					
AMX/CA 500 mg/125 mg	500	6.5	1.50	23.2	1.3
Amoxicillin 500 mg	125	6.5	1.3	19.5	1.1
Clavulanic acid					
AMX/CA 500 mg/125 mg	125	2.8	1.3	7.3	0.8
Clavulanic acid 125 mg	125	3.4	0.9	7.8	0.7
AMX: Amoxicillin, CA: Clavulanic acid - * Median					

Amoxicillin and clavulanic acid serum concentrations achieved with Amoxicillin/clavulanic acid combination are similar to those produced by the oral administration of equivalent doses of each alone.

Distribution:
Following intravenous administration therapeutic concentrations of both amoxicillin and clavulanic acid may be detected in the tissues and interstitial fluid. Therapeutic concentrations of both medicines have been found in gall bladder, abdominal tissue, skin, fat, and muscle tissues; fluids found to have therapeutic levels include synovial and peritoneal fluids, bile and pus.

Neither amoxicillin nor clavulanic acid is highly protein bound, studies show that about 13-25% of total plasma drug content of each compound is bound to protein.
From animal studies there is no evidence to suggest that either component accumulates in any organ.

Amoxicillin, like most penicillins, can be detected in breast milk. Trace quantities of clavulanate can also be detected in breast milk. With the exception of the risk of sensitization associated with this excretion, there are no known detrimental effects for the breastfed infant.

Reproduction studies in animals have shown that both amoxicillin and clavulanic acid penetrate the placental barrier. However, no evidence of impaired fertility or harm to the foetus was detected.

Biotransformation:
Amoxicillin is partly excreted in the urine as the inactive penicilloic acid in quantities equivalent to up to 10-25% of the initial dose. Clavulanic acid is extensively metabolized in man as metabolized to 2.5-dehydro-4-(2-hydroxyethyl)-5-oxo-1H-pyrol-3-carboxylic acid and 1-amino-4-hydroxy-butane-2-one and eliminated in urine and faeces and as carbon dioxide in expired air.

Elimination:
As with other penicillins, the major route of elimination for amoxicillin is via the kidney, whereas for clavulanic acid it is by both renal and non-renal mechanisms.

Approximately 60-70% of the amoxicillin and approximately 40-65% of the clavulanic acid are excreted unchanged in urine during the first 6 hours after administration of a single 500/125 mg tablet or a single 500/100 mg or a single 1000/200 mg bolus intravenous injection.

Concomitant use of probenecid delays amoxicillin excretion but does not delay renal excretion of clavulanic acid (see section 4.5).

5.3 Preclinical safety data
No further information of relevance.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients
Silicon dioxide
Microcrystalline cellulose
Carmellose sodium
Sucralose
Sodium citrate anhydrous
Citric acid anhydrous
Silica colloidal anhydrous
Mannitol
Xanthan gum 13
Vanilla flavour (Maize maltodextrin, Triacetin E1518, Modified corn starch E1450, Vanillin, Myrrh absolute (commiphora molmol), Isopentanol)

Tutti-frutti flavour (Maize maltodextrin, Prolylene glycol E1520, Benzyl alcohol, Orange oil (citrus sinesis), Vanillin, Ethyl butyrate)

6.2 Incompatibilities
There is no known incompatibility.

6.3 Shelf life
Dry powder: 36 months
Liquid suspension: 7 days.

6.4 Special precautions for storage
Dry powder: Store below 25°C in the original package in order to protect from light and moisture.
Liquid suspension: Reconstituted suspension should be stored at 2°C–8°C (Refrigerate, do not freeze).

6.5 Nature and contents of container
Amber coloured glass bottle of 100 ml, 125 ml or 200 ml closed with child-resistant, tamper evident polypropylene screw cap with aluminium foil liner. Once made up, the bottle contains 35 ml or 70 ml (100 ml bottle), 100 ml (125 ml bottle) or 140 ml (200 ml bottle) of the suspension.
Not all pack sizes may be marketed.
Each pack contains a 5 ml dosing syringe (polypropylene/polyethylene) with 0.5 mL graduation marks and an adaptor for the syringe (polyethylene).

6.6 Special precautions for disposal and other handling
Any unused material should be disposed according to local disposal regulations.

Preparation of AMOXICLAV Devatis Duo suspension:
1. Tap bottle until all powder flows freely.
2. Add approximately 2/3 of total water for reconstitution. Shake vigorously to wet the powder.

3. Add water up to the mark on the bottle (remaining 1/3) and shake well again.
4. The dose recommended by your doctor is given to the patient using a syringe that is supplied with the bottle.

Volume of water to be added at reconstitution (ml)	Final volume of reconstituted oral suspension (ml)
32	35
62	70
87	100
122	140

Shake the bottle well before each dose.
After reconstitution of the powder the medicinal product is a white to creamy white suspension.

Instructions for using the syringe
A syringe is supplied to administer AMOXICLAV Devatis Duo
The syringe is only for use with AMOXICLAV Devatis Duo and must not be used to administer any other medicines, because the markings are specific to this product. The syringe is supplied with an adaptor which allows it to attach to the bottle.

The dose is indicated on the oral dosing syringe in millilitres (ml). You should give your child the dose recommended by their doctor.
Check cleanliness of syringe before use, rinse with clean water if required.

1. Shake the bottle suspension well before each dose.
2. Remove adaptor from syringe. Hold the bottle firmly and insert the adaptor into the neck of the bottle (the adaptor should remain in place).
3. Insert the syringe into the adaptor ensuring it is secure.
4. Invert bottle holding the syringe in place and withdraw the required dose as indicated by your doctor.
5. Place bottle upright and remove syringe.
6. To give the dose, carefully put the tip of the syringe into the mouth and slowly push down on the plunger of the syringe (repeat steps 3, 4, 5 and 6 if more than one syringe is needed to deliver the dose).
7. Rinse syringe thoroughly in clean water. Allow the syringe to dry completely before next use.
8. Replace the bottle cap.
9. Store in a refrigerator and always shake before use. Once made up, the suspension should be used within 7 days.

7. MEDICINE SCHEDULE

Prescription Medicine

8. SPONSOR

DEVATIS LIMITED
45 Yarrow Street,
Invercargill 9810, New Zealand
Tel: +64 3 211 0080
Fax: +64 3 211 0079
www.devatis.nz

9. DATE OF FIRST APPROVAL

Date of first authorization: 16.01.2020
Date of latest renewal:

10. DATE OF REVISION OF THE TEXT

21.03.2024