

NEW ZEALAND DATA SHEET

Curam

Amoxicillin Trihydrate Ph, Eur, and Potassium Clavulanate Ph, Eur., film-coated tablet, 250 + 125 mg, powder for oral suspension, 125 + 31.25 mg/5 ml and 250 + 62.5 mg/5 ml (as amoxicillin/clavulanic acid)

Curam Duo 500/125

Amoxicillin Trihydrate Ph. Eur. and Potassium Clavulanate Ph. Eur., film-coated tablet, 500 + 125 mg (as amoxicillin/clavulanic acid)

Presentations

Curam tablets

250 + 125 mg

Tablet, film-coated, oblong biconvex formed, off-white colour. Scored on both sides. Each tablet contains Amoxicillin Trihydrate Ph. Eur. equivalent to amoxicillin 250 mg and Potassium Clavulanate Ph. Eur. equivalent to clavulanic acid 125 mg.

Curam Duo 500/125 tablets

Tablet, film-coated, oval biconvex formed, off-white colour. Scored on both sides. Each tablet contains Amoxicillin Trihydrate Ph. Eur. equivalent to amoxicillin 500 mg and Potassium Clavulanate Ph. Eur. equivalent to clavulanic acid 125 mg.

Curam powder for oral suspension

125 + 31.25 mg/5 ml

Suspension, oral, powder for, white to yellowish colour. Reconstituted suspension contains in 5 ml, Amoxicillin Trihydrate Ph. Eur. equivalent to amoxicillin 125 mg and Potassium Clavulanate Ph. Eur. equivalent to clavulanic acid 31.25 mg.

250 + 62.5 mg/5 ml

Suspension, oral, powder for, white to yellowish colour. Reconstituted suspension contains in 5 ml, Amoxicillin Trihydrate Ph. Eur. equivalent to amoxicillin 250 mg and Potassium Clavulanate Ph. Eur. equivalent to clavulanic acid 62.5 mg.

Indications

Short term treatment of common bacterial infections 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

Dosage in renal impairment

Dosing adjustments are based on the maximum recommended level of amoxicillin.

Adults

Mild impairment (creatinine clearance >30 ml/min): no change in dosage. Moderate impairment (creatinine clearance 10 to 30 ml/min): 1 tablet 12 hourly. For severe impairment (creatinine clearance <10 ml/min): 1 tablet once daily. Dialysis decreases serum concentrations of amoxicillin/clavulanic acid. An additional dose may need to be supplemented at the end of dialysis.

Children

Oral suspension (in the majority of cases, parenteral therapy, where available, may be preferred). Mild impairment (creatinine clearance >30 ml/min): no change in dosage. Moderate impairment (creatinine clearance 10 to 30 ml/min) 15 + 3.75 mg/kg given 12 hourly (maximum 500 + 125 mg twice daily). Severe impairment (creatinine clearance <10 ml/min) 15/3.75mg/kg given as a single daily dose (maximum 500 + 125 mg). Dialysis decreases serum concentrations of amoxicillin/clavulanic acid. Prior to haemodialysis 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 haemodialysis.

Dosage in 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.

Dosage in 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 above).

Administration

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

Curam oral suspensions

To minimise potential gastrointestinal intolerance, administer at the start of a meal. The absorption of amoxicillin/clavulanic acid is optimised when taken at the start of a meal.

Treatment should not be extended beyond 14 days without review.

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

Contraindications

Hypersensitivity to one of the constituents of the medicine.

Hypersensitivity to other beta-lactams such as penicillins and cephalosporins.

Previous history of jaundice or hepatic dysfunction associated with amoxicillin/clavulanic acid.

Warnings and precautions

Before initiating therapy with amoxicillin/clavulanic acid, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, or other allergens. Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity. If an allergic reaction occurs, amoxicillin/clavulanic acid therapy should be discontinued and appropriate alternative therapy instituted. Serious anaphylactoid reactions require

immediate emergency treatment with adrenaline or epinephrine. Oxygen, intravenous steroids and airway management, including intubation may also be required.

Amoxicillin/clavulanic acid 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.

In general amoxicillin/clavulanic acid 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 haematopoietic function is advisable during prolonged therapy.

Abnormal prolongation of prothrombin time (increased INR) has been reported rarely in patients receiving amoxicillin/clavulanic acid and oral anticoagulants. Appropriate monitoring should be undertaken when anticoagulants are prescribed concomitantly. Adjustments in the dose of oral anticoagulants may be necessary to maintain the desired level of anticoagulation.

Amoxicillin/clavulanic acid should be used with caution in patients with evidence of hepatic dysfunction.

In patients with renal impairment, dosage should be adjusted according to the degree of impairment (refer to Dosage and administration).

Amoxicillin/clavulanic acid suspensions contain aspartame, which is a source of phenylalanine and should be used with caution in patients with phenylketonuria.

In patients with reduced urine output crystalluria has been observed very rarely, predominantly with parenteral therapy. During 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 (refer to Overdosage).

Use in pregnancy

Assigned Category B1 by the Australian Drug Evaluation Committee. This category includes medicines which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed. Studies in animals have not shown evidence of an increased occurrence of foetal damage.

Reproduction studies in animals (mice and rats at doses up to 10 times the human dose) with orally and parenterally administered amoxicillin/clavulanic acid have shown no teratogenic effects. In a single study in women presenting 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 necrotising enterocolitis in neonates. As with all medicines, use should be avoided in pregnancy, unless considered essential by the physician.

Use in lactation

Amoxicillin/clavulanic acid may be administered during the period of lactation. With the exception of the risk of sensitisation, associated with the excretion of trace quantities in breast milk, there are no known detrimental effects for the breastfed infant.

Effects on ability to drive and use machines

This medicine is presumed to be safe or unlikely to produce an effect. Adverse effects on the ability to drive or operate machinery have not been observed.

Adverse effects

Data from large clinical trials were used to determine the frequency of very common to rare adverse effects. The incidences of all other adverse effects occurring below 1 in 10,000 were mainly determined from post-marketing data and reflect the reporting rate rather than the true incidence.

Very common (incidence 1 in 10 or more)

Gastrointestinal tract

Diarrhoea.

Common (incidence from 1 in 100 to 1 in 10)

Gastrointestinal tract

Nausea, vomiting. In all populations nausea is more often associated with higher oral dosages. If gastrointestinal reactions are evident, they may be reduced by taking amoxicillin/clavulanic acid at the start of a meal. Lower gastro-intestinal irritation reactions such as diarrhoea and pruritus ani have been observed. These side-effects are generally of a mild and transitory nature.

Infections and infestations

Mucocutaneous candidiasis.

Skin and subcutaneous tissues

Allergic skin reactions occur significantly more often than with other penicillins and generally are maculopapular in nature. In a small majority of cases, "fifth day rash" (a morbilliform exanthema) is reported. This is dependent on the size of the dose and the patient's condition.

Uncommon (incidence from 1 in 1000 to 1 in 100)

Gastrointestinal tract

Indigestion.

Hepatobiliary tract

A moderate rise in AST and/or ALT values has been noted in patients treated with beta-lactam antibiotics, but the significance of these findings is unknown.

Nervous system

Dizziness, headache.

Skin and subcutaneous tissues

Typical type I allergic reactions such as skin rash, pruritis, urticaria and purpura; angio-oedema and anaphylaxis can occur less frequently.

Rare (incidence from 1 in 10,000 to 1 in 1,000)

Blood and lymphatic system

Abnormalities of the blood count, usually reversible such as leucopenia (including neutropenia) and thrombocytopenia.

Cardiovascular system

In rare cases, allergies can result in anaphylactic shock.

Skin and subcutaneous tissues

Erythema multiforme.

Very rare (incidence below 1 in 10,000)

Blood and lymphatic system

Reversible agranulocytosis and haemolytic anaemia. Prolongation of bleeding and prothrombin time (refer to [Warnings and precautions](#))

Gastrointestinal tract

Antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis). 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.

Hepatobiliary tract

Hepatitis and cholestatic jaundice associated with amoxicillin/clavulanic acid and other beta-lactam antibiotics have been reported rarely. Hepatic effects occur predominantly in males and elderly patients, particularly those over 65 years of age. These side-effects are very rarely reported in children. The incidence appears to increase with treatment courses exceeding 14 days. Signs and symptoms usually occur during or shortly after treatment, but in some cases may not become apparent until several weeks after treatment cessation. Hepatic effects are usually transient and reversible. However, they may be severe and in extremely rare cases, a fatal outcome has been reported. These have mostly occurred in patients with a serious underlying disease, or patients taking potentially hepatotoxic agents in addition to amoxicillin/clavulanic acid.

Immune system disorders

Angioneurotic oedema, anaphylaxis, serum sickness-like syndrome, hypersensitivity vasculitis.

Nervous system

Reversible hyperactivity and convulsions. Convulsions may occur in patients with impaired renal function or in those receiving high doses.

Skin and subcutaneous tissues

Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous exfoliative dermatitis, acute generalised exanthematous pustulosis (AGEP). The appearance of skin hypersensitivity reactions warrants discontinuation of amoxicillin/clavulanic acid treatment.

Urogenital tract

Interstitial nephritis and crystalluria (refer to [Overdosage](#))

Laboratory diagnostic tests

Non-enzymatic methods for glucose determination in urine may give false-positive results.

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

Interactions

Amoxicillin/clavulanic acid injection must not be administered concomitantly with bacteriostatic agents, such as tetracyclines, macrolides and chloramphenicol, particularly in acute infections.

A number of agents can inhibit the renal tubular secretion of amoxicillin but not clavulanic acid. Inhibitors include probenecid, phenylbutazone, oxyphenbutazone and to a lesser extent, acetylsalicylic acid, indomethacin and sulfinpyrazone. As inhibition of renal tubular secretion prolongs the half-life and increases plasma levels of amoxicillin only, concomitant use of probenecid is not recommended.

Concomitant use of allopurinol during treatment with amoxicillin can increase the risk of allergic skin reactions. There are no data on the concomitant use of amoxicillin/clavulanic acid and allopurinol.

Concomitant use of amoxicillin and oral contraceptives is associated with the incidence of breakthrough bleeding and possibly reduced activity of the oral contraceptives. Amoxicillin/clavulanic acid may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives.

Amoxicillin can partially eradicate the gastrointestinal flora and therefore potentially increase the absorption of concomitantly administered digoxin.

In the literature there are rare 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.

Concurrent administration of amoxicillin/clavulanic acid and disulfiram is poorly tolerated. Therefore, amoxicillin/clavulanic acid injection should not be used concomitantly with disulfiram.

Overdose

Drug dependency, addiction and recreational abuse have not been reported as problems.

Signs and symptoms

Gastrointestinal symptoms and disturbance of fluid and electrolyte balances may be evident.

Complications from amoxicillin crystalluria may present in high doses, in some cases leading to renal failure (refer to [Warnings and precautions](#)). When present at high concentrations in urine at room temperature, amoxicillin may precipitate in bladder catheters. A regular check of patency should be maintained.

Management

Amoxicillin and clavulanic acid can be removed from the circulation by haemodialysis. Gastrointestinal symptoms may be treated symptomatically by attending to the water and electrolyte balance. Treat other symptoms symptomatically. A prospective study of 51 paediatric patients at a poison control centre suggested that overdosages less than 250 mg/kg of amoxicillin are not associated with significant clinical symptoms and do not require gastric emptying.

Further information

Actions

Curam film-coated tablets and oral suspension are antibiotic preparations compounded for oral administration from amoxicillin trihydrate – a beta-lactam antibacterial penicillin and the potassium salt of clavulanic acid - a beta-lactamase inhibitor. Amoxicillin/clavulanic acid has a notably broad spectrum of activity against bacterial pathogens of clinical importance to general practice and secondary/tertiary care.

Pharmacotherapeutic group

J01CR02 – Combinations of penicillins, including beta-lactamase inhibitors.

Mechanism of action

Refer to [Antibiotic nature and mode of action](#).

Pharmacodynamic effects

Refer to [Antibiotic nature and mode of action](#).

Antibiotic class

Semi-synthetic penicillin compounded with a beta-lactamase inhibitor.

Antibiotic nature and mode of action

Amoxicillin is an aminopenicillin type broad spectrum antibiotic that possesses activity against many Gram-positive and Gram-negative micro-organisms. Amoxicillin is a bactericidal, cell-wall active agent that inhibits bacterial cell wall synthesis by binding to penicillin binding proteins and inhibits the cross-linking of bacterial peptidoglycan. However, amoxicillin is susceptible to degradation by beta-lactamases so its intrinsic spectrum of activity excludes bacteria producing these enzymes.

Clavulanic acid is a beta-lactam, structurally related to the penicillins. It 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.

When appropriately combined with amoxicillin, clavulanic acid inhibits the degradation of amoxicillin by beta-lactamase enzymes and effectively extends the antibacterial spectrum of amoxicillin to include many bacteria normally resistant to amoxicillin, other penicillins and cephalosporins.

Susceptibility data

The prevalence of resistance may vary geographically and temporally for selected species. Local resistance information is desirable, particularly when treating severe infections. The following information only provides approximate guidance on the probabilities that micro-organisms will be susceptible to amoxicillin/clavulanic acid.

Susceptible

Susceptible Gram-positive aerobes include: *Bacillus anthracis*[1], *Corynebacterium* spp., *Enterococcus faecalis*[1], *Listeria monocytogenes*, *Nocardia asteroides*, *Staphylococcus aureus*[1], Coagulase negative staphylococci[1] (including *Staphylococcus epidermidis*[1]), *Streptococcus* spp.; *Streptococcus pneumoniae*; Group A streptococci (including *Streptococcus pyogenes*); Group B streptococci (including *Streptococcus agalactiae*); Viridans group streptococci.

Susceptible Gram-positive anaerobes include: *Clostridium* spp., *Peptococcus* spp., *Peptostreptococcus* spp.

Susceptible Gram-negative aerobes include: *Bordetella pertussis*, *Brucella* spp., *Gardnerella vaginalis*, *Haemophilus influenzae*[1], *Helicobacter pylori*, *Legionella* species, *Moraxella catarrhalis*[1], *Neisseria gonorrhoeae*[1], *Neisseria meningitidis*[1], *Pasteurella multocida*, *Proteus mirabilis*[1], *Proteus vulgaris*[1], *Vibrio cholerae*, *Yersinia enterocolitica*[1].

Susceptible Gram-negative anaerobes include: *Bacteroides* spp.[1] (including *Bacteroides fragilis*), *Fusobacterium* spp.[1]

Other susceptible pathogens include: *Borrelia burgdorferi*, *Chlamydiae* spp., *Leptospira icterohaemorrhagiae*, *Treponema pallidum*.

Intermediate

Partially susceptible Gram-positive aerobes include *Enterococcus faecium*[1].

Partially susceptible Gram-negative aerobes include: *Escherichia coli*[1]; *Klebsiella* spp.[1]; *Klebsiella pneumoniae*[1]; *Klebsiella oxytoca*[1]; *Salmonella* spp.[1]; *Salmonella hadar*[1]; *Salmonella typhimurium*[1]; *Shigella* spp.[1].

Notes:

[1] some members of these species of bacteria produce beta-lactamase, rendering them insensitive to amoxicillin alone.

Resistance

Although, amoxicillin/clavulanic acid may exhibit *in vitro* activity against methicillin/oxacillin resistant *Staphylococcus aureus* (MRSA) and coagulase-negative staphylococci (MRS) it is not clinically effective and isolates should therefore be considered resistant. Rare beta-lactamase negative, ampicillin resistant (BLNAR) strains of *H. influenzae* should also be considered resistant to amoxicillin/clavulanic acid despite the apparent *in vitro* susceptibility of some BLNAR strains.

Resistant Gram-positive aerobes include *Staphylococcus aureus* (MRSA) and Coagulase-negative staphylococci (MRS).

Resistant Gram-negative aerobes include: *Acinetobacter* spp.; *Citrobacter* spp.; *Enterobacter* spp.; *Haemophilus influenzae* (BLNAR); *Morganella morganii*; *Providencia* spp.; *Pseudomonas aeruginosa*; *Serratia* spp.; *Stenotrophomonas maltophilia*.

Other resistant pathogens include *Mycoplasma* spp. and *Rickettsia* spp.

Clinically relevant MIC ranges

According to the US National Committee on Clinical Laboratory Standards (NCCLS) in 2001, the following breakpoints have been defined for amoxicillin/clavulanic acid:

Enterobacteriaceae: NMT 8/4 mcg/ml susceptible, 16/8 mcg/ml intermediate, NLT 32/16 mcg/ml resistant;

Staphylococcus spp. and *Haemophilus* spp.: NMT 4/2 mcg/ml susceptible, NLT 8/4 mcg/ml resistant;

Streptococcus pneumoniae: NMT 2/1 mcg/ml susceptible, 4/2 mcg/ml intermediate, NLT 8/4 mcg/ml resistant;

Anaerobic bacteria: NMT 4/2 mcg/ml susceptible, 8/4 mcg/ml intermediate, NLT 16/8 mcg/ml resistant.

No NCCLS breakpoint is stipulated for *Vibrio cholerae*, however, ampicillin susceptibility (NMT 8 mcg/ml susceptible, 16 mcg/ml intermediate, NLT 32 mcg/ml resistant) is representative for amoxicillin/clavulanic acid.

For *Enterococcus* spp. penicillin and ampicillin susceptibility (NMT 8 mcg/ml susceptible, NLT 16 mcg/ml resistant) may be used to predict the susceptibility to amoxicillin/clavulanic acid.

Pharmacokinetics

Absorption

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 amoxicillin/clavulanic acid is optimised when taken at the start of a meal.

Two separate studies measured the mean pharmacokinetic parameters in fasting healthy volunteers for amoxicillin/clavulanic acid 625 mg tablets equivalent to amoxicillin 500 mg and clavulanic acid 125 mg against the two components given separately. Following a single oral dose equivalent to amoxicillin 500 mg: amoxicillin/clavulanic acid 625 mg gave a plasma concentration-time profile characterised by a peak corresponding to C_{max} of 6.5 mg/l at t_{max} of 1.5 hours with AUC of 23.2 mg.h/l and elimination half life of 1.3 hours; amoxicillin 500 mg alone gave a plasma concentration-time profile characterised by a peak corresponding to C_{max} of 6.5 mg/l at t_{max} of 1.3 hours with AUC of 19.5 mg.h/l and elimination half life of 1.1 hours. Similarly, following a single oral dose equivalent to clavulanic acid 125 mg: amoxicillin/clavulanic acid 625 mg gave a plasma concentration-time profile characterised by a peak corresponding to C_{max} of 2.8 mg/l at t_{max} of 1.3 hours with AUC of 7.3 mg.h/l and elimination half life of 0.8 hours; clavulanic acid 125 mg alone gave a plasma concentration-time profile characterised by a peak corresponding to C_{max} of 3.4 mg/l at t_{max} of 0.9 hours with AUC of 7.8 mg.h/l and elimination half life of 0.7 hours. The studies suggest that

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

Distribution

Intravenous administration of the prescribed dose of amoxicillin/clavulanic acid provides therapeutic levels of both constituents in the tissues and interstitial fluids including gall bladder, skin, abdominal, adipose and muscle tissues, synovial and peritoneal fluids, bile and pus. Neither amoxicillin nor clavulanic acid is highly protein bound, studies show that about 13% to 25% of total plasma drug content of each compound is bound to protein. From animal studies there is no evidence to suggest that either compound 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 sensitisation 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

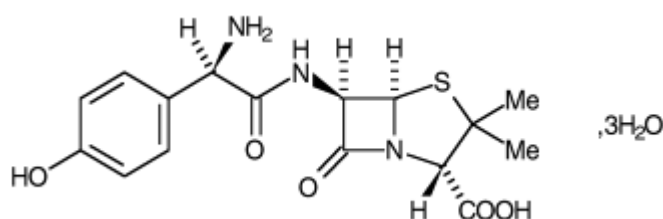
Amoxicillin is partly metabolised with between 10 to 25% of the initial dose found in the urine as the inactive penicilloic acid. Clavulanic acid is extensively metabolised. The inactive metabolites 2,5-dihydro-4-(2-hydroxyethyl)-5-oxo-1H-pyrrole-3-carboxylic acid and 1-amino-4-hydroxy-butan-2-one are eliminated by urinary and biliary excretion while the terminal metabolite, carbon dioxide, is eliminated in expired air and water.

Elimination

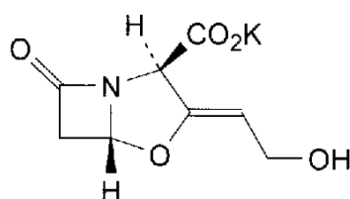
As with other penicillins, the major route of elimination for amoxicillin is via the kidney, whereas for clavulanate it is by both renal and non-renal mechanisms. Approximately 60 to 70% of the amoxicillin content and approximately 40 to 65% of the clavulanic acid content are excreted unchanged in urine during the first 6 hours after administration of a single 500/125 mg tablet.

Chemical structure

Amoxicillin trihydrate



Potassium clavulanate



List of excipients

Curam tablets

Microcrystalline cellulose, croscarmellose sodium, talc, povidone, magnesium stearate, titanium dioxide, hypromellose, ethylcellulose, sodium lauryl sulfate, cetyl alcohol, triethyl citrate.

Curam powder for oral suspension

Colloidal silicon dioxide, guar gum, aspartame, talc, trisodium citrate, citric acid, orange flavour, lemon flavour, peach-apricot flavour.

These medicines do not contain lactose or gluten.

Pharmaceutical precautions

Instructions for use/handling

Reconstitution instructions

Curam powder for oral suspension 125 mg/5 ml: add water 95 ml to make up 100 ml.

Curam powder for oral suspension 250 mg/5 ml: add water 90 ml to make up 100 ml.

Close and shake well at once. Store the prepared suspension under refrigeration (2 to 8°C) and use within 7 days of preparation. Shake well before use.

Incompatibilities

None known.

Shelf life

Unopened container:

Curam tablets: 36 months.

Curam powder for oral suspension: 36 months.

After container first opened:

Not applicable.

After dilution or reconstitution:

Curam tablets: not applicable.

Curam powder for oral suspension: 7 days when stored at 2 to 8°C (refrigerate, do not freeze).

Special precautions for storage

Store below 25°C. Protect from moisture.

Package quantities

Curam 250mg/125mg tablets

Packs of 15, 21 and 100 tablets in blister strips.

Curam Duo 500/125 tablets

Packs of 10, 15, 21 and 100 tablets in blister strips. Curam powder for oral suspension

Bottles of 60 and 100 ml.

All presentations, strengths or pack sizes may not be currently marketed.

Medicine schedule

Prescription Medicine.

Sponsor details

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28 January 2011