		ok	ok	ok	ok	ok
Amoxyclav Tablets Originator vs Generic Package Inserts						
	Augmentin 375 Originator (SKB)	**Clamentin**	**Augmaxcil 375 (Triomed)**	**Adco-Amoclav 375 mg (Al)**	**Clavumox 375 mg(Group Labs)**	**Ranclav 375mg**
1. INDICATIONS						
Upper respiratory tract infections (caused by amoxycillin-resistant organisms producing β-lactamases sensitive to clavulanic acid) eg. Sinusitis, recurrent otitis media, tonsilitis	x	x	x	x	x	x
Lower respiratory tract infections eg.bronchitis (caused by amoxycillin-resistant β-lactamase-producing E. coli, H. influenzae and H. parainfluenzae), bronchopneumonia	x	x	x	x	x	x
Genito-urinary tract infections (caused by amoxycillin-resistant organisms producing β-lactamases sensitive to clavulanic acid) eg. Cystitis, urethritis, pyelonephritis	x	x	x	x	x	x
Skin and soft tissue infections	x	x	x	x	x	x
Infections caused by amoxycillin-sensitive organisms at the appropriate amoxycillin dosage	x	x	N	x	x	x
Total	5	5	4	5	5	5
p=Proportion		p=5/5=1.00	p=4/5=0.80	p=5/5=1.00	p=5/5=1.00	p=5/5=1.00
2. DOSAGE						
Dosage for amoxycillin sensitive organisms is as approved for amoxycillin - clavulanic acid does not contribute to efficacy	x	x	N	x	x	x
Usual adult dose: 1-2 x 375 mg tablets q8h at start of meal	x	x	N	x	x	x
Impaired renal function: serum half life of both components increased in renal failure. Reduce dose or extend dosing interval based on max recommended dose of amoxycillin	x	x	x	x	x	x
Mild renal impairment:(Cr Cl > 30ml/min):no change	x	x	x	x	x	x
Moderate renal impairment: (Cr Cl 10-30 ml/min): 1 tablet q12h	x	x	x	x	x	x
Severe renal impairment: Cr Cl < 10 ml/min: half tablet q12h	x	x	N	x	x	x
Amoxycillin-sensitive organisms - URTI, LRTI, UTI, Skin & Soft Tissue Infections: 1-2 x 375 mg q8h	x	x	x	x	x	x
Amoxycillin-resistant organisms - **URTI** (otitis media) - H. influenzae, H. parainfluenzae; 2 x 375 mg q8h. **LRTI** (bronchitis) - H. influenzae, H. parainfluenzae; 2 x 375 mg **UTI** E. coli, Klebsiella pneumoniae 1-2 x 375 mg q8h; **Skin & Soft Tissue Infections**: S. aureus: 1- 2 x 375 mg	x	x	x	x	x	x
Total	8	8	6	8	8	8
p=Proportion		p=8/8=1.00	6/8=0.75	p=8/8=1.00	p=8/8=1.00	p=8/8=1.0
3. CAUTIONS						
Warnings						
Serious/occasionally fatal hypersensitivity (anaphylactoid) reactions esp in pts with history of penicillin hypersensitivity and/or history of sensitivity to multiple allergens	x	x	x	x	x	x
Careful inquiry concerning previous hypersensitivity reactions to penicillins, cephalosporins & other allergens before initiating therapy	x	x	x	x	x	x
If allergic reaction occurs, discontinue & institute appropriate therapy - adrenaline, corticosteroids & antihistamines	x	x	x	x	x	x
Transient hepatitis and cholestatic jaundice - use with caution in pts with hepatic dysfunction	x	x	x	x	x	x
Total	4	4	4	4	4	4
p=Proportion		p=4/4=1.00	p=4/4=1.00	p=4/4=1.00	p=4/4=1.00	p=4/4=1.00
Contra-indications						
Allergy to penicillins and cephalosporins	x	x	x	x	x	x
Safety in pregnancy has not been established	x	x	x	x	x	x
Previous history of jaundice/hepatic dysfunction associated with the product	x	x	x	x	x	x
Total	3	3	3	3	3	3
p=Proportion		p=3/3=1.00	p=3/3=1.00	p=3/3=1.00	p=3/3=1.00	p=3/3=1.00
Special precautions						
Periodic assessment of renal, hepatic and haemopoeitic function advisable during prolonged therapy	x	x	x	N	x	N
Not treatment of choice in pts with sore throat or pharyngitis (cause likely to be mononucleosis, due to high incidence of rash with amoxycillin	x	x	N	x	x	N
Caution in lymphatic leukaemia due to susceptibility to amoxycillin-induced skin rashes	x	x	N	N	x	N
Superinfections with mycotic or bacterial pathogens (usually Aerobacter, Pseudomonas or Candida)	x	x	x	x	x	x
Severe hepatic dysfunction, use with care - changes in liver function tests	x	x	N	x	x	x
Moderate or severe renal impairment, dosage adjustment required	x	x	N	x	x	x
Amoxycillin is secreted in breast milk. Trace quantities of clavulanate detected in breast milk. No known detrimental effects for breast-fed infant, except risk of sensitisation	x	N	N	N	N	x
Total	7	6	2	4	6	4
p=Proportion		p= 6/7 = 0.8	p=2/7 = 0.29	p= 4/7 =0.57	p=6/7=0.86	p=4/7=0.57

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Overall Cautions	14	13 p=13/14 =0.	9 p=9/14=0.64	11 p=11/14=0.79	13 p=13/14=0.9	14 ok p=11/14=0.
4. SIDE-EFFECTS						
Most common=diarrhoea, nausea, vomiting, indigestion, abdominal pain, skin rashes, urticaria, erythema multiforme, vaginitis, abnormal taste, headache, dizziness, tiredness, hot flushes	x	x	N	N	x	N
Hepatic effects						
Hepatitis	x	x	x	x	x	x
Cholestatic jaundice	x	x	x	x	x	x
Rise in AST and/or ALT	x	x	N	x	x	x
Effects on the gastrointestinal tract						
Gastritis	x	x	N	N	x	N
Stomatitis	x	x	x	x	x	x
Glossitis	x	x	x	x	x	x
Black 'hairy' tongue	x	x	x	x	x	x
Enterocolitis	x	x	N	N	x	N
Mucocutaneous candidiasis	x	N	x	N	N	N
Antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis)	x	x	x	x	x	x
GIT effects reduced by taking at the start of a meal	x	x	x	N	x	N
Hypersensitivity reactions:						
Skin rashes	x	x	x	x	x	x
Pruritis	x	N	N	N	N	N
Urticaria	x	x	x	x	x	x
Serum sickness-like syndrome	x	N	N	N	N	N
Erythema muliforme	x	x	x	x	x	x
Stevens-Johnson syndrome	x	x	x	x	x	x
Hypersensitivity vasculitis	x	N	N	x	N	N
Bullous exfoliative dermatitis	x	x	N	x	x	x
Toxic epidermal necrolysis	x	x	x	x	x	x
Serious/occasionally fatal hypersensitivity (anaphylactic) reactions and angioneurotic oedema	x	x	x	x	x	x
Interstitial nephritis	x	N	N	x	N	x
Haematopoietic and lymphatic						
Haemolytic anaemia	x	N	x	N	N	N
Reversible thrombocytopenia	x	x	N	x	x	x
Thrombocytopenic pupura	x	x	N	x	x	x
Eosinophilia	x	x	N	x	x	x
Leucopenia	x	x	N	x	x	x
Agranulocytosis	x	x	N	x	x	x
Thrombocytosis	x	x	N	N	x	N
Prolonged bleeding time & prothrombin time	x	x	N	N	x	N
Central Nervous System effects:						
Reversible hyperactivity	x	N	N	x	N	x
Dizziness	x	x	N	x	N	x
Headache	x	x	N	N	N	N
Convulsions (impaired renal function or high doses)	x	N	N	x	N	N
Miscellaneous						
Superficial tooth discolouration	x	N	N	N	N	N
Total	36	27	15	24	25	22
p=Proportion		p=27/36=0.7	p=20/36=0.4	p=24/36=0.67	p=25/36=0.6	p=22/36=0.
5. DRUG INTERACTIONS						
Probenecid decreases renal tubular secretion of amoxycillin (increased & prolonged blood levels) , but does not affect clavulanate excretion	x	x	x	x	x	x
Allopurinol - possible increase in skin rashes (as with ampicillin) but no data available	x	x	x	x	x	N
Alcohol and some beta-lactam antibiotics has precipitated a disulfiram (Antabuse) reaction - therefore avoid alcohol during and for several days after therapy	x	x	N	N	x	N
May reduce efficacy of oral contraceptives (reduced conjugated oestrogens)	x	x	N	x	x	x
May lead to selection of resistant strains of organisms - sensitivity testing advisable whenever possible	x	x	N	N	x	N
Total	5	5	2	3	5	2
p=Proportion		p=5/5=1.00	p=2/5=0.40	p=3/5=0.60	p=5/5=1.00	p=2/5=0.40
Date of Publication	1999/03/05	Oct-95	Jul-97	Mar-00	April 996	May-02

Mean of p values=Overall p value 1.00+0.80 +1.00+1.00+1.00÷5=0.96

q=1.00-0.96=0.04
pq=0.96x0.04=0.04
Std Deviation=√(pq÷n)=√(0.04÷5)=√0.01=0.09
95% CI = p±(2.776xStd Dev) = p±(2.776x0.09)=p±0.25
95%CI = 0.96±0.25 ie. 1.21 to 0.71

0

Mean of p values=Overall p value 1.00+0.75 +1.00+1.00+1.00÷5=0.95

q=1.00-0.95=0.05
pq=0.95x0.05=0.05
Std Deviation=√(pq÷n)=√(0.05÷5)=√0.01=0.1
95% CI = p±(2.776xStd Dev) = p±(2.776x0.1)=p±0.28
95%CI = 0.95±0.28 ie. 1.23 to 0.67

0

0

Mean of p values=Overall p value 0.93+0.64 +0.79+0.93+0.79÷5=0.82

q=1.00-0.82=0.18
pq=0.82x0.18=0.15
Std Deviation=√(pq÷n)=√(0.15÷5)=√0.03=0.17
95% CI = p±(2.776xStd Dev) = p±(2.776x0.17)=p±0.47
95%CI = 0.82±0.47 ie. 1.29to 0.354
7

).79

Mean of p values=Overall p value 0.75+0.42 +0.67+0.69+0.61÷5=0.63

q=1.00-0.63=0.37
pq=0.63x0.37=0.23
Std Deviation=√(pq÷n)=√(0.23÷5)=√0.05=0.22
95% CI = p±(2.776xStd Dev) = p±(2.776x0.22)=p±0.61
95%CI = 0.63±0.61 ie. 1.24to 0.02

).61

Mean of p values=Overall p value 1.0+0.40 +0.60+1.0+0.40÷5=0.68

q=1.00-0.68=0.32
pq=0.68x0.32=0.22
Std Deviation=√(pq÷n)=√(0.22÷5)=√0.04=0.21
95% CI = p±(2.776xStd Dev) = p±(2.776x0.22)=p±0.58
95%CI = 0.68±0.58 ie. 1.26 to 0.10
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