

The study listed may include approved and non-approved uses, formulations or treatment regimens. The results reported in any single study may not reflect the overall results obtained on studies of a product. Before prescribing any product mentioned in this Register, healthcare professionals should consult prescribing information for the product approved in their country.

Study No.: Augmentin SSTIs 103997	
Title: An Open, Non-comparative study to evaluate the Efficacy & Safety of Augmentin 1 g (875 mg amoxicillin/125 mg clavulanic acid) po q 12 hours in the Treatment of Uncomplicated Skin and Soft tissue Infections in Pakistan.	
Rationale: The study of marketed drug is to provide local data to determine the efficacy and safety of 875mg amoxicillin/125mg clavulanic acid po q 12 hours for the treatment of uncomplicated skin and soft tissues infections.	
Phase: IV	
Study Period: Dec 2004 - Mar 2005	
Study Design: Open label, non-comparative multicentre study.	
Centres: Four centres in Pakistan	
Indication: Uncomplicated Skin and soft tissue infections.	
Treatment: 875 mg amoxicillin/125mg clavulanic acid)po q 12 hours for 5-10 days.	
Objectives: To assess the efficacy and safety of 875 mg amoxicillin/125mg clavulanic acid po q 12 hours in the treatment of uncomplicated skin and soft tissue infections in Pakistan.	
Primary Outcome/Efficacy Variable: Clinical response at follow-up (10-14 days post therapy) is the primary endpoint.	
Secondary Outcome/Efficacy Variable(s): 1. Clinical response at on-therapy evaluation visit (2-4 days following initiation of therapy) 2. Clinical response at end of therapy (48-96 hours post-therapy) 3. Bacteriological response on-therapy evaluation visit (2-4 days following initiation of therapy) 4. Bacteriological response at end of therapy (48-96 hours post-therapy) 5. Bacteriological response on follow-up visit (at 10-14 days post-therapy) 6. Safety analysis through assessment of changes in physical examination, vital signs, clinical laboratory test and adverse experiences.	
Statistical Methods: Descriptive	
Study Population: Male or female subjects, at least 12 years of age with a) furuncle, carbuncle or simple abscess (not requiring major incision and drainage) b) impetigo or secondarily infected lesions, or c) cellulitis (with or without a known portal of entry). Key exclusion criteria were: known hypersensitivity to penicillins, cephalosporins or other beta-lactams; signs of systemic toxicity (high fever > 102 F, or hypotension); prior antibiotic therapy within two weeks of study; local or systemic steroid use within 24 hrs prior to study entry; use of an investigational compound within one month prior to entering the study; serious underlying uncontrolled medical condition; pre-existing renal or hepatic insufficiency; known amoxicillin/clavulanic acid -associated cholestatic jaundice/hepatic dysfunction; pregnancy or lactation; requirement for surgical intervention for treatment of infection.	
	875 mg amoxicillin/125mg clavulanic acid
Number of Subjects:	
Planned, N	200
Randomised, N	201
Completed, n (%)	186 (92.5)
Total Number Subjects Withdrawn, N (%)	15 (7.5)
Withdrawn due to Adverse Events n (%)	0
Withdrawn due to Lack of Efficacy n (%)	0
Withdrawn for other reasons n (%)	15 (100)
Demographics	
N (ITT)	201
Females: Males	69:132
Mean Age, years (SD)	Not yet available
Punjabi, n (%)	124 (62)
Primary Efficacy Results: Not yet available	

Secondary Outcome Variable(s): Not yet available	
Safety Results: All subjects who have received at least one dose of study medication will be assessed for clinical safety	
Most Frequent Adverse Events – On-Therapy	875 mg amoxicillin/125mg clavulanic acid n (%)
Subjects with any AE(s), n(%)	0
List specific AEs according to guidance above	N/A
Serious Adverse Events - On-Therapy n (%) [n considered by the investigator to be related to study medication]	
	n (%) [related]
Subjects with non-fatal SAEs, n (%)	0
Subjects with fatal SAEs, n (%)	0
Conclusion: Analysis of data is still ongoing. Only Serious Adverse Event data are available. Full results will be posted once the analysis is complete.	
Publications: No Publication	

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