




		EMLc	ATC codes: R01AD05
Indication	Allergic rhinitis	ICD11 code: CA07.0Z	
INN	Budesonide		
Medicine type	Chemical agent		
List type	Core		
Formulations	Local > Nasal > Spray: 100 µg per dose (EMLc)		
EML status history	First added in 2009 (TRS 958)		
Sex	All		
Age	Children (1 month - 12 years)		
Therapeutic alternatives	Medicines within the same pharmacological class can be used		
Patent information	Patents have expired in most jurisdictions Read more <a href="#">about patents</a> . 		
Wikipedia	<a href="#">Budesonide</a> 		
DrugBank	<a href="#">Budesonide</a> 		

### Summary of evidence and Expert Committee recommendations

In 2009, the EMLc Subcommittee considered the review that was commissioned to identify essential medicines for the treatment of ear, nose and throat conditions in children. Based primarily on South African guidelines and WHO guidelines for treating ear, nose and throat conditions in children, the priority conditions identified were acute croup, epiglottitis, epistaxis, otitis externa, otitis media (acute and chronic), rhinosinusitis and sore throat. The Subcommittee noted that many medicines required for treating these conditions were already listed. However, several more needed to be considered for addition. These included preparations for both topical and systemic use. There was a lack of documented evidence for the efficacy and safety of most of the medicines that needed to be considered for addition. Most available data came from studies in adults or from those involving both adults and children. However, these medicines are recommended in widely accepted guidelines. The Subcommittee noted that there is evidence to show that antibiotic ear drops are of benefit in the treatment of otitis externa. There is evidence to suggest that quinolone ear drops are superior to other otic antimicrobial formulations. The Subcommittee considered the importance of the available information regarding combination antimicrobial agent–corticosteroid formulations for the treatment of otitis externa (1) and found no compelling evidence to support the inclusion of combination products. The Subcommittee therefore recommended that acetic acid ear drops and ciprofloxacin ear drops be added to the EMLc, the ciprofloxacin ear drops with a square box annotation. The Subcommittee decided that based on available evidence, the inclusion of a nasal corticosteroid could be recommended. Further, the Subcommittee recommended the inclusion of a decongestant nasal spray/nose drops, listing xylometazoline with a square box annotation. Topical ephedrine was not included in recognition of its potential for abuse. 1. Rosenfeld RM et al. Systematic review of topical antimicrobial therapy for acute otitis externa. *Otolaryngology and Head and Neck Surgery*, 2006, 134(4 Suppl):S24–48.

