DEPARTMENT OF HEALTH

MEDICINES CONTROL AGENCY

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Product Licences Granted

Product Licence Number	*Company Name*	*Product Name*	*Active Ingredients*	*Indications*	*Date of Authorisation*
0006/0266	Lilly Industries Limited, T/A Eli Lilly and Company Limited; Dista Products Limited; Greenfield Pharmaceuticals	Lorabid Capsules 200 mg	Loracarbef (Monohydrate) HSE 210.3 mg Equivalent to Loracarbef 200.0 mg	Prescription Only Medicine Treatment of the following infections, in both adults and children over 6 months of age, when caused by susceptible strains of the designated organisms. Otitis media caused by streptococcus pneumoniae, haemophilus influenzae (including beta-lactamase producing strains), moraxella catarrhalis (including beta-lactamase producing strains), streptococcus pyogenes (group A beta-haemolytic streptococci) and staphylococcus SP. Acute bronchitis and acute exacerbations of chronic bronchitis caused by S pneumoniae, H influenzae (including beta-lactamase producing strains), haemophilus parainfluenzae, M. Catarrhalis (including beta-lactamase producing strains), klebsiella pneumoniae, neisseria meningitidis, staphylococcus aureus, S. Pyogenes (group A beta-haemolytic streptococci) and viridans streptococci. Pneumonia caused by S pneumoniae, H influenzae (including beta-lactamase producing strains), H parainfluenzae and M catarrhalis (including beta-lactamase producing strains). Sinusitis caused by S pneumoniae, H influenzae (including beta-lactamase producing strains), M catarrhalis (including beta-lactamase producing strains) and S pyogenes (group A beta-haemolytic streptococci). Pharyngitis and tonsillitis caused by S pyogenes (group A beta-haemolytic streptococci). Loracarbef is generally effective in the eradication of stretococci from the oropharynx. Uncomplicated lower urinary tract infections, including cystitis and asymptomatic bacteriuria caused by escherichia coli, K pneumoniae, proteus mirabilis and staphylococcus saprophyticus. Uncomplicated pyelonephritis caused by E coli and P mirabilis. Skin and skin structure infections caused by S pyogenes (group A beta-haemolytic streptococci), S aureus and staphylococcus epidermidis. Bacteriological studies to determine the causative organism and its susceptibility to Loracarbef should be performed. Therapy may be started while awaiting the results of these studies. Once these results become available, antimicrobial therapy should be adjusted accordingly. Loracarbef is inactive against most strains of Acinetobacter, Enterobacter, Morganella morganii, Proteus vulgaris, Providencia, Pseudomonas and Serratia. Most anaerobes are resistant to Loracarbef, as are methicillin-resistant staphylococci.	12th April, 1994