

DEPARTMENT OF HEALTH

MEDICINES CONTROL AGENCY

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Product Licences Granted

<i>Product Licence Number</i>	<i>Company Name</i>	<i>Product Name</i>	<i>Active Ingredients</i>	<i>Indications</i>	<i>Date of Authorisation</i>
00012/0318	May & Baker Limited	Suprax Powder for Paediatric Oral Suspension	Cefixime Anhydrous 100 000 mg	It is an orally active cephalosporin antibiotic which has marked in vitro bactericidal activity against a wide variety of Gram-positive and Gram-negative organisms. It is indicated for the treatment of the following acute infections when caused by susceptible micro-organisms: Upper respiratory tract infections e.g. otitis media, and other URTI where the causative organisms is known or suspected to be resistant to other commonly used antibiotics, or where treatment failure may carry significant risk. Lower respiratory tract infections. Urinary tract infections e.g. cystitis, cystourethritis, pyelonephritis. Clinical efficacy has been demonstrated in infections caused by commonly occurring pathogens including <i>Streptococcus pneumoniae</i> , <i>Streptococcus pyogenes</i> , <i>Escherichia coli</i> , <i>Proteus mirabilis</i> , <i>Klebsiella</i> species, <i>Haemophilus influenzae</i> (beta-lactamase positive and negative), <i>Branhamella catarrhalis</i> (beta-lactamase positive and negative) and <i>Enterobacter</i> species. It is highly stable in the presence of beta-lactamase enzymes. Most strains of enterococci (<i>Streptococcus faecalis</i> , group D <i>Streptococci</i>) and <i>Staphylococci</i> (including coagulase positive and negative strains and methicillin-resistant strains) are resistant to it. In addition, most strains of <i>Pseudomonas</i> , <i>Bacteroides fragilis</i> , <i>Listeria monocytogenes</i> and <i>Clostridia</i> are resistant to it. Prescription Only Medicine.	14th October 1998
00041/0058	Bioglan Laboratories Limited	Tramadol Hydrochloride Tablets 50 mg	Tramadol Hydrochloride 50 000 mg	Management (treatment and prevention) of moderate to severe pain. Prescription Only Medicine.	12th October 1998
00053/0265	Schering Health Care Ltd	Mircna	Levonorgestrel 52 000 mg	Contraception. Prescription Only Medicine.	30th September 1998
00065/0155	Organon Laboratories Limited	Pregnyl 5000IU	Chorionic Gonadotrophin 5000 000 iu	In the male: Hypogonadotrophic hypogonadism. Delayed puberty associated with insufficient gonadotrophic pituitary function. Sterility in selected cases of deficient spermatogenesis. In the female: Sterility due to the absence of follicle-ripening or ovulation. In conjunction with HMG, in the promotion of controlled superovulation, in medically assisted reproduction programmes. Prescription Only Medicine.	3rd July 1998
0095/0319	Cyanamid of Great Britain Ltd	Zoton Suspension 30 mg	Lansoprazole 30 000 mg	It is effective in the treatment of acid-related disorders of the upper gastro-intestinal tract, with the benefit of rapid symptom relief. It is also effective in combination with antibiotics in the eradication of <i>Helicobacter pylori</i> (<i>H. pylori</i>). The suspension may be particularly useful for patients who have difficulty swallowing, such as the elderly or patients with oesophageal strictures or dysphagia caused by severe oesophagitis. Indications: Healing and long term management of Gastro Oesophageal Reflux Disease (GORD). Healing and maintenance therapy for patients with duodenal ulcer. Relief of reflux-like symptoms (eg heartburn) and/or ulcer-like symptoms (eg upper epigastric pain) associated with acid-related dyspepsia. Healing of benign gastric ulcer. It is also effective in patients with benign peptic lesions, including reflux oesophagitis unresponsive to H2 receptor	28th July 1998