



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>
00002/0235	SmithKline & French Laboratories Limited	Tagamet HB	Cimetidine 200.000mg	<p>Prescription Only Medicine</p> <p>It is a histamine H2-receptor antagonist which rapidly inhibits both basal and stimulated gastric secretion of acid and reduces pepsin output. Indicated in the treatment of duodenal and benign gastric ulceration, including that associated with non-steroidal anti-inflammatory agents, recurrent and stomal ulceration, and oesophageal reflux disease. Also in other conditions where reduction of gastric acid by cimetidine has been shown to be beneficial, including: persistent dyspeptic symptoms with or without ulceration, particularly meal-related upper abdominal pain. including such symptoms associated with non-steroidal anti-inflammatory agents. The prophylaxis of gastrointestinal haemorrhage from stress ulceration in seriously ill patients. Before general anaesthesia in patients thought to be at risk of acid aspiration (Mendelson's) syndrome, particularly obstetric patients during labour. To reduce malabsorption and fluid loss in short bowel syndrome and in pancreatic insufficiency to reduce degradation of enzyme supplements. It is also recommended in the management of the Zollinger-Ellison syndrome.</p>	13th April 1999
00011/0239	John Wyeth & Brother Limited	Premique Cycle	<p>Conjugated Oestrogens .625mg</p> <p>Conjugated Oestrogens .625mg</p> <p>Medroxyprogesterone Acetate 10.000mg</p>	<p>Prescription Only Medicine</p> <p>For the treatment of the following conditions in women with an intact uterus:</p> <ol style="list-style-type: none"> 1. Vasomotor symptoms associated with oestrogen deficiency 2. Atrophic vaginitis 3. Atrophic urethritis 4. The prevention and management of osteoporosis associated with oestrogen deficiency in women at risk of developing fractures. <p>Epidemiological studies suggest a number of individual risk factors which contribute to the development of post-menopausal osteoporosis. These include early menopause; family history of osteoporosis; thin, small frame; cigarette smoking; recent prolonged systemic corticosteroid use. If several of these risk factors are present in a patient, consideration should be given to oestrogen replacement therapy.</p>	30th April 1999
00022/0182	Pharmacia Laboratories Limited	Glipizide 5mg Tablets	Glipizide 5.000mg	<p>Prescription Only Medicine</p> <p>As an adjunct to diet, in non-insulin-dependent diabetics (NIDDM), when proper dietary management alone has failed.</p>	24th June 1999
00031/0520	Roche Products Limited	Loron Capsules	Clodronate Disodium Tetrahydrate 499.790mg	<p>Prescription Only Medicine</p> <p>For the management of osteolytic lesions, hypercalcaemia and bone pain associated with skeletal metastases in patients with carcinoma of the breast or multiple myeloma. Also for the maintenance of clinically acceptable serum calcium levels in patients with</p>	1st July 1999