

DEPARTMENT OF HEALTH
MEDICINES CONTROL AGENCY

Market Towers, 1 Nine Elms Lane, London SW8 5NQ. Telephone 071-273 0422 or 0425

Product Licences Authorised

<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>
11723/0158	Sanofi Winthrop Limited (<i>v/a</i> Sterwin Medicines)	Diclofenac Sodium Tablets 25 mg	Diclofenac Sodium HSE 25-00 mg	Adults: Rheumatoid arthritis; osteoarthritis; low back pain; acute musculo-skeletal disorders such as peri-arthritis, tendinitis, tenosynovitis, bursitis, sprains, sprains and dislocation; relief of pain in fractures; ankylosing spondylitis; acute gout; control of pain and inflammation in orthopaedic, dental and other minor surgery. Children: Juvenile chronic arthritis. POM	30th September 1994
11723/0159	Sanofi Winthrop Limited (<i>v/a</i> Sterwin Medicines)	Diclofenac Sodium Tablets 50 mg	Diclofenac Sodium HSE 50-00 mg	See PL/11723/0158.	30th September 1994
11723/0160	Sanofi Winthrop Limited (<i>v/a</i> Sterwin Medicines)	Atenolol Tablets 50 mg BP	Atenolol BP 50-0 mg	May be used in the management of hypertension, angina pectoris and cardiac dysrhythmias, also as an adjunct in the early management of acute myocardial infarction. POM	30th September 1994
11723/0161	Sanofi Winthrop Limited (<i>v/a</i> Sterwin Medicines)	Atenolol Tablets 100 mg BP	Atenolol BP 100-0 mg	See PL/11723/0160.	30th September 1994
11723/0164	Sanofi Winthrop Limited (<i>v/a</i> Sterwin Medicines)	Allopurinol Tablets BP 100 mg BP	Allopurinol BP 100 mg	1. Conditions of excess body urate including gout. Allopurinol is used to reduce urate levels in the body when these levels are excessive (serum is theoretically saturated with urate at a concentration between 0.38-0.42 mmol (6.4-7.0 mg %)). The higher levels seen in practice may be accounted for by (a) the formation of supersaturated solutions; (b) protein binding of urate. Excess body urate may be indicated by hyperuricaemia and/or hyperuricosuria. It may lead to deposition of urate in the tissues or it may be present with no obvious signs or symptoms. The main clinical manifestations of urate deposition are gouty arthritis, skin tophi and/or renal involvement. Excess body urate is frequently of idiopathic origin but may also be found in association with other conditions including the following: neoplastic disease and its treatment; certain enzyme disorders (in particular Lesch Nyhan syndrome); renal failure; renal calculus formation; diuretic therapy and psoriasis. 2. Calcium renal lithiasis: Allopurinol is of benefit in the prophylaxis and treatment of calcium renal lithiasis in patients with raised serum or urinary uric acid. POM	30th September 1994
11723/0165	Sanofi Winthrop Limited (<i>v/a</i> Sterwin Medicines)	Allopurinol Tablets BP 300 mg BP	Allopurinol BP 300 mg	See PL/11723/0164.	30th September 1994
11723/0168	Sanofi Winthrop Limited (<i>v/a</i> Sterwin Medicines)	Fenbufen Capsules 300 mg	Fenbufen HSE 300 mg	For the symptomatic treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis and acute musculoskeletal disorders. POM	30th September 1994
11723/0169	Sanofi Winthrop Limited (<i>v/a</i> Sterwin Medicines)	Fenbufen Tablets 300 mg	Fenbufen HSE 300-0 mg	See PL/11723/0168.	30th September 1994
11723/0170	Sanofi Winthrop Limited (<i>v/a</i> Sterwin Medicines)	Diltiazem Hydrochloride Tablets 60 mg	Diltiazem Hydrochloride USP 60-0 mg	Angina pectoris. POM	30th September 1994
11723/0171	Sanofi Winthrop Limited (<i>v/a</i> Sterwin Medicines)	Spirolactone Tablets BP 25 mg	Spirolactone BP 25-0 mg	Congestive cardiac failure, hepatic cirrhosis with ascites and oedema, malignant ascites, nephrotic syndrome, diagnosis and treatment of primary aldosteronism. POM	30th September 1994
11723/0172	Sanofi Winthrop Limited (<i>v/a</i> Sterwin Medicines)	Spirolactone Tablets BP 50 mg	Spirolactone BP 50-0 mg	See PL/11723/0171.	30th September 1994
11723/0173	Sanofi Winthrop Limited (<i>v/a</i> Sterwin Medicines)	Spirolactone Tablets BP 100 mg	Spirolactone BP 100-0 mg	See PL/11723/0171.	30th September 1994
11723/0174	Sanofi Winthrop Limited (<i>v/a</i> Sterwin Medicines)	Co-flumactone Tablets 25/25	Spirolactone BP 25-0 mg Hydroflumethiazide BP 25-0 mg	Congestive cardiac failure. POM	30th September 1994