PRESCRIBING INFORMATION

Sulfinpyrazone 100mg and 200mg tablets (sulfinpyrazone)

Presentation: Coated tablets

Indication: Chronic, including tophaceous gout; recurrent gouty arthritis; hyperuricaemia

Dosage and administration: *Route of administration:* Oral. *Adults*: 100-200mg daily increasing gradually (over the first two or three weeks) to 600mg daily (rarely 800mg), and maintained until the serum urate level has fallen within the normal range. Maintenance dose may be as low as 200mg daily. *Children*: Paediatric usage not established.

Contraindications: Acute attacks of gout. Gastric and duodenal ulcer. Known hypersensitivity to sulfinpyrazone and other pyrazolone derivatives. Contra-indicated in patients with asthma, urticaria, or acute rhinitis, severe parenchymal lesions of the liver or kidneys, porphyria, blood dyscrasias, haemorrhagic diatheses

Precautions and warnings: Used with caution in patients with hyperuricaemia or gout, episodes of urolithiasis or renal colic, ensure adequate fluid intake and alkalinisation of the urine during initial stages of therapy. Sulfinpyrazone may cause salt and water retention hence caution is called for in patients with overt or latent heart failure. For the early detection of a haematological abnormality, careful clinical supervision and full blood count should be done before and at regular intervals during treatment. Use with caution in patients with impaired renal function. In patients with an elevated plasma uric acid level and/or with a history of nephrolithiasis or renal colic, and when resuming treatment after interruption of the medication, a cautious incremental dosage schedule should be adopted. For long-term use of uricosuric medication, continuous monitoring of renal function tests should be performed.

Interactions: Coumarin-type anticoagulants, hypoglycaemic agents, sulphonamides, penicillin, theophylline, phenytoin, non-steroidal antirheumatic drugs.

Pregnancy and lactation: Used with caution in pregnant women, weighing the potential risk against the possible benefits. It is not known whether the active substance or its metabolite(s) pass into breast milk. For safety reasons mothers should refrain from taking the drug.

Undesirable effects: Mild transient gastro-intestinal upsets, such as nausea, vomiting, diarrhea, gastro-intestinal bleeding and ulcers, acute renal failure, salt and water retention, allergic skin reactions, leucopenia, thrombocytopenia, agranulocytosis, aplastic anaemia, hepatic dysfunction, jaundice and hepatitis.

(Please refer to the Summary of Product Characteristics for detailed information)

Overdose: Nausea, vomiting, abdominal pains, diarrhoea, hypotension, cardiac arrhythmias, hyperventilation, respiratory disorders, impairment of consciousness, coma, epileptic seizures, oliguria or anuria, acute renal failure, renal colic. Treatment: Immediate treatment consists of forced emesis to recover undigested tablets followed by gastric lavage preferably with mild alkaline solution such as sodium bicarbonate solution.

Legal category: POM

Basic NHS cost: 100mg tablets £41.25 for pack size of 84
200mg tablets £79.00 for pack size of 84

Marketing Authorisation Number: 100 mg: PL 20072/0024
200 mg: PL 20072/0025

Marketing Authorisation Holder: Amdipharm Mercury Company Limited (AMCo), 1st Floor, Capital House, 85 King William Street, London, EC4N 7BL.

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Adverse events should be reported to the local regulatory authority.
Reporting forms and information can be found at **www.mhra.gov.uk/yellowcard**
Adverse events should also be reported to **Amdipharm Mercury Medical Information** at **08700 70 30 33** or via e-mail to **medicalinformation@amcolimited.com**