

Actonel 5mg**ABBREVIATED PRESCRIBING INFORMATION:**

PRESENTATION: ACTONEL 5mg film coated tablets contain the equivalent of 4.64 mg risenedronic acid. **INDICATIONS:** Treatment of established postmenopausal osteoporosis: to reduce the risk of vertebral fractures. Prevention of osteoporosis in postmenopausal women with increased risk of osteoporosis. To maintain or increase bone mass in postmenopausal women undergoing long-term (more than 3 months), systemic corticosteroid treatment at doses $\geq 7.5\text{mg/day}$ prednisone or equivalent. **DOSAGE AND ADMINISTRATION:** 5mg once a day orally. Take Actonel either: at least 30 minutes before the first food or drink (other than water) of the day OR at least 2 hours from any food or drink at any other time of the day, and at least 30 minutes before going to bed. Do not suck or chew the tablets. Actonel is to be taken while in an upright position with a glass of plain water ($\geq 120\text{ ml}$). Do not lie down for 30 minutes after taking Actonel. *Children:* Safety and efficacy has not been established in children and adolescents. **CONTRAINDICATIONS:** Known hypersensitivity to risedronate sodium or to any of its excipients, hypocalcaemia, pregnancy and lactation, severe renal impairment (creatinine clearance $<30\text{ml/min}$). **PRECAUTIONS:** Foods, drinks (other than plain water) and drugs containing polyvalent cations may interfere with the absorption of Actonel. Caution should be used in patients who have a history of oesophageal disorders which delay oesophageal transit or who are unable to stay in the upright position for at least 30 minutes. Hypocalcaemia should be treated before starting therapy. Other disturbances of bone and mineral metabolism should be treated at the start of therapy. *Interactions:* No formal interaction studies have been performed, however no clinically relevant interactions with other medicinal products were found. Actonel is not systemically metabolised. *Use in pregnancy and lactation:* Actonel must not be used during pregnancy or by breast-feeding women. **SIDE EFFECTS:** The majority of undesirable effects observed in clinical trials were mild to moderate in severity. The overall safety profile of Actonel 5mg was similar to placebo. The following adverse reactions were reported by the investigators as possibly or probably drug related in $>1/100$ $<1/10$ patients treated with Actonel 5mg/day (N=1916) and at an incidence greater than placebo (N=1914): dyspepsia (Actonel 5.2%, vs placebo 4.6%), abdominal pain (4.1%, 3.4%), constipation (3.7%, 3.6%), diarrhoea (2.9%, 2.6%), flatulence (2.0%, 1.8%), gastritis (1.1%, 0.8%), musculoskeletal pain (2.3%, 2.2%), headache (2.3%, 2.2%), rash (1.4%, 1.0%). The following adverse reactions associated with bisphosphonates were reported by the investigators as possibly or probably drug related in $>1/1000$ patients: nausea (Actonel 4.9%, vs placebo 5.0%), oesophagitis (0.9%, 0.9%), duodenitis (0.4%, 0.1%), dysphagia (0.3%, 0.2%), oesophageal ulcer (0.2%, 0.3%), oesophageal stricture (0.1%, 0.0%), glossitis (0.1%, 0.0%). **PACK QUANTITIES AND BASIC NHS COST:** £21.83 for 28 tablets POM. Date of preparation March 2000. **PRODUCT LICENCE NUMBER:** PL 00364/0070, PA 170/20/1 **PRODUCT LICENCE HOLDER:** Procter & Gamble Pharmaceuticals UK Ltd, Lovett House, Lovett Road, Staines, Middlesex, TW18 3AZ, UK. Refer to Summary of Product Characteristics before prescribing. Further information is available from Medical Information at the address above. A1345