Stirlescent 250 mg Effervescent Tablets® – Abbreviated Prescribing Information

Please refer to the appropriate Summary of Product Characteristics (SmPC) before prescribing naproxen 250 mg effervescent tablets.

Each tablet contains 250 mg of naproxen with 341.89 mg of sodium and the following excipients – anhydrous citric acid, sodium hydrogen carbonate, anhydrous sodium carbonate, sodium cyclamate, saccharin sodium, sodium citrate, povidone K30, macrogol 6000, mannitol, simeticone, docusate sodium and flavour Cassis 'NAP', code 410. **Indications:** For the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, acute musculoskeletal disorders, dysmenorrhoea and acute gout in patients aged 18 years or over with a creatinine clearance of at least 30 ml/min. **Dosage and administration: Rheumatoid arthritis, osteoarthritis and ankylosing spondylitis:** Initially 250 mg twice daily, increasing if necessary to 500 mg twice daily. **Acute musculoskeletal conditions and dysmenorrhoea:** Initial dose of 500 mg followed by 250 mg every 6–8 hours. Maximum dose after the first day is 5 tablets daily. **Acute gout:** Initial dose of 750 mg followed by 250 mg every 8 hours until the attack has passed. **Elderly patients:** Use the lowest effective dose for the shortest possible duration. **Renal/Hepatic impairment:** Consider lowering the dose in patients with renal or hepatic impairment. **Method of administration:** Doses of 1 to 2 tablets must be dissolved in at least 150 ml (a glass) of water and doses of 3 to 4 tablets must be dissolved in 300 ml of water. Preferably to be taken with or after food. **Contraindications:** Hypersensitivity to the active drug or any of the other excipients, Active peptic ulcer or GI haemorrhage, History of recurrent peptic ulceration, perforation or GI haemorrhage, previous hypersensitivity reactions to aspirin, ibuprofen or other NSAIDs, Severe hepatic, renal or cardiac failure. Stirlescent should not be administered at the same time as any other NSAID. Use with caution in patients with asthma or allergic disorders hypertension or mild to moderate congestive heart failure. Patients at high risk of GI bleeding, ulceration or perforation should be considered for co-prescribing of a gastroprotective agent such as misoprostol or a proton pump inhibitor. Caution is necessary in patients receiving other medication that could increase the risk of ulceration or bleeding such as oral corticosteroids, warfarin, low dose aspirin, other NSAIDs, antiplatelet agents or selective serotonin-reuptake inhibitors. Stirlescent should be discontinued at the first sign of a skin rash, mucosal lesion or any other sign of hypersensitivity. Monitoring of renal function is recommended in patients with impaired renal function, cardiac impairment, liver dysfunction, those taking diuretics, angiotensin converting enzyme inhibitors, angiotensin-II receptor antagonists and the elderly. **Interaction with other medicinal products** Refer to the SmPC for detailed advice. **Use in pregnancy and lactation:** Stirlescent is contraindicated in the third trimester. Do not use naproxen during labour or breastfeeding. Do not use during the first two trimesters unless the benefits outweigh the perceived risks. **Ability to drive and use machinery:** If affected by dizziness, drowsiness do not drive or operate machinery. **Overdose:** Refer to the SmPC for detailed advice. **Undesirable effects:** gastrointestinal disorders, hypersensitivity reactions, oedema, palpitations, congestive heart failure, hypertension, cardiac failure, small increased risk of thrombotic arterial events, nephrotoxicity, hepatitis, visual disturbance, retrobulbar optic neuritis, headaches, light-headedness, paraesthesia, convulsions, dizziness,

vertigo, drowsiness, cognitive dysfunction, inability to concentrate, aseptic meningitis, tinnitus, thrombocytopenia, neutropenia, granulocytopenia, aplastic anaemia, eosinophilia, leucopoenia, haemolytic anaemia, skin rashes including fixed drug eruption, pruriti, urticaria, ecchymoses, purpura, sweating, angioedema, alopecia, erythema multiforme, bullous reactions including Stevens-Johnson syndrome, Drug Reaction Eosinophilia and Systemic Symptoms (DRESS), erythema nodosum, lichen planus, pustular reaction, SLE, epidermal necrolysis, myalgia, muscle weakness, female infertility, thirst, pyrexia, fatigue, malaise, dyspnoea, asthma, eosinophilic pneumonitis, pulmonary oedema, hyperkalaemia, insomnia, dream abnormalities, depression, hallucinations. Please refer to the SmPC for a full list of undesirable effects. **Legal category**: POM **Pack size:** 20 effervescent tablets in polypropylene tubes with desiccant included in the stopper. **Shelf life:** 36 months.
NHS list price: 20 effervescent tablets = £52.72
Marketing Authorisation Holder: Stirling Anglian Pharmaceuticals Ltd, Hillington Park Innovation Centre, 1 Ainslie Road, Hillington Park, Glasgow G52 4RU, United Kingdom. **Marketing Authorisation Number:** PL42582/0009**.** Further information is available at medinfo@stirlinganglianpharmaceuticals.com or via the office number **0345 527 0680. Date of preparation:** October 2024
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Adverse events should be reported. Reporting forms and information can be found at **http://yellowcard.mhra.gov.uk** or downloaded from Google Play or the Apple App store. Adverse events should also be reported to JensonR+ on **01271 334 609** or Stirling Anglian Pharmaceuticals on **0345 527 0680**.