**Feminax® Ultra 250 mg Gastro-resistant tablets** (naproxen). **Indications:** Treatment of primary dysmenorrhoea in women aged 15 to 50 years. **Dosage and Administration:** Day 1 - two tablets (500 mg) followed by one tablet (250 mg) after 6 to 8 hours if needed. Days 2 and 3 - one tablet (250mg) every 6 to 8 hours if needed. Maximum dose is three tablets daily. Maximum duration of continuous treatment in any one cycle is three days. Swallowed whole, not to be crushed or chewed. **Contraindications:** History of, or active peptic ulceration or gastrointestinal bleeding (two or more episodes of proven ulceration or bleeding). History of gastrointestinal perforation related to previous non-steroidal anti-inflammatory drug (NSAID) therapy. Hypersensitivity. Aspirin or NSAID induced asthma, rhinitis, nasal polyps, angioedema or urticaria. Severe heart failure, hepatic or renal failure (baseline creatinine clearance of less than 30ml/minute). During the last trimester of pregnancy. **Warnings & Precautions:** Use the lowest effective dose for the shortest duration necessary to control symptoms. Long term users of NSAIDs should undergo regular supervision to monitor for adverse events. Anti-inflammatory and antipyretic effects may diminish utility of diagnostic signs: inflammation and fever. As with other NSAIDs, elevations of one or more liver function tests may occur. Severe hepatic reactions have been reported with this and other NSAIDs. Cross reactivity has been reported. Risk of sodium retention in those with questionable or compromised cardiac function. Avoid use with concomitant NSAIDs, including cyclooxygenase-2 selective inhibitors. Caution in patients with a history of cardiovascular and cerebrovascular events due to a small increased risk of arterial thrombotic events. Patients with cardiac impairment should only use naproxen under the doctor’s supervision. Use only after careful consideration in patients with: uncontrolled hypertension, congestive heart failure, established ischaemic heart disease, peripheral arterial disease, cerebrovascular disease and patients with risk factors for cardiovascular disease (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking). Reports of impaired renal function, renal failure, acute interstitial nephritis, haematuria, proteinuria, renal papillary necrosis and occasionally nephrotic syndrome associated with naproxen. Caution in gastrointestinal disease, impaired renal or hepatic function, patients with a history of ulcer and patients receiving concomitant medications which could increase the risk of gastro-intestinal ulceration or bleeding. These patients should commence treatment on lowest dose available. If GI bleeding or ulceration occurs, treatment should be withdrawn. Anaphylactic (anaphylactoid) reactions may occur. May elicit bronchospasm in patients with a history of asthma or allergic disease. Naproxen decreases platelet aggregation and prolongs bleeding time. Patients with coagulation disorders should be carefully observed. Discontinue treatment at the first appearance of skin rash, mucosal lesion, or any other sign of hypersensitivity. Use with steroids only under supervision of a doctor. Patients who develop visual disturbances during treatment should undergo ophthalmological examination. In Systemic Lupus Erythematosus and mixed connective tissue disorders, risk of aseptic meningitis. Women who first experience period pain more than a year after starting menstruation should only take naproxen on the advice of a doctor. Naproxen may impair fertility and is therefore not recommended in women wishing to conceive. Contains lactose. Should not be taken by patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. **Use in pregnancy:** Should not be used during pregnancy or lactation except on the advice of a doctor. **Side-effects:** Most commonly gastrointestinal. Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, heartburn, epigastric distress, gastro-intestinal ulceration (which is sometimes fatal), peptic ulceration, perforation, non-peptic gastro-intestinal ulceration, melena, haematemes is, stomatitis, ulcerative stomatitis, exacerbation of colitis and Crohn’s disease and oesophagitis have been reported. Less frequently, gastritis has been observed.
Pancreatitis has been reported very rarely. Hypersensitivity reactions have been reported following treatment with NSAIDs and may consist of (a) non-specific allergic reactions and anaphylaxis (b) respiratory tract reactivity comprising asthma, aggravated asthma, bronchospasm or dyspnoea, or (c) assorted skin disorders, including rashes of various types, pruritus, urticaria, purpura, angioedema and, less commonly, exfoliative and bullous dermatoses (including epidermal necrolysis, erythema multiforme and Stevens-Johnson Syndrome). Oedema, palpitations, hypertension, vasculitis, cardiac failure, congestive heart failure and aseptic meningitis have been reported (especially in patients with existing auto-immune disorders, e.g., systemic lupus erythematosus, connective tissue disease) with symptoms such as stiff neck, headache, nausea, vomiting, fever or disorientation. Use of coxibs and some NSAIDs (particularly at high doses and in long term treatment) may be associated with a small increased risk of arterial thrombotic events. Other adverse events reported less commonly include: Nephrotoxicity, including glomerular nephritis, interstitial nephritis, nephrotic syndrome, haematuria, raised serum creatinine, renal papillary necrosis and renal failure. Abnormal liver function, fatal hepatitis and jaundice. Visual disturbances, corneal opacity, papillitis and papilloedema, optic neuritis, headaches, paraesthesia, depression, confusion, hallucinations, tinnitus, hearing impairment, vertigo, dizziness, convulsions, insomnia, dream abnormalities, inability to concentrate, cognitive dysfunction, light headedness, thirst, fever, malaise, fatigue and drowsiness. Dyspnoea, asthma, eosinophilic pneumonitis and pulmonary oedema. Myalgia and muscle weakness. Thrombocytopenia, neutropenia, agranulocytosis, aplastic anaemia, hyperkalaemia and haemolytic anaemia. Photosensitivity, alopecia. Bullous reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis (very rare). Fixed drug eruption, itching, urticaria, ecchymoses, purpura, sweating, erythema multiforme, erythema nodosum, lichen planus, pustular reaction, SLE, epidermal necrolysis or epidermal bullous-like reactions may occur rarely. If skin fragility, blistering or symptoms of pseudoporphyrina, treatment should be discontinued and patient monitored. **RRP (Excl VAT):** £3.95  **MA Number:** PL 00289/0699. **MA Holder:** TEVA UK Limited, Eastbourne, BN22 9AG. **Distributor:** Bayer plc, Consumer Care Division, Newbury, Berkshire, RG14 1JA. **Legal Category:** P **Date of Preparation:** May 2012 Feminax® Ultra is a Registered trademark of Bayer AG.