Prescribing Information: Keral (dexketoprofen) 25 mg film–coated tablets.
Please consult the Summary of Product Characteristics (SmPC) for full prescribing information.
Presentation: Each film-coated tablet contains 25 mg of dexketoprofen trometamol.
Use: Symptomatic treatment of pain of mild to moderate intensity, such as musculo-skeletal pain, dysmenorrhoea, dental pain.
Dosage and administration: Oral administration. Adults: According to the nature and severity of the pain. Recommended dosage is 12.5 mg every 4-6 hours or 25 mg every 8 hours. Total daily dose should not exceed 75 mg. Undesirable effects may be minimised by using the lowest effective dose for the shortest duration to contain symptoms. Treatment should be limited to the symptomatic period. Elderly: Recommended to start therapy at 50 mg total daily dose. Dosage may be increased to the recommended once good general tolerance has been observed. Hepatic impairment: Patients with mild to moderate hepatic dysfunction should start therapy at 50 mg total daily dose and be closely monitored. Contraindicated in patients with severe hepatic dysfunction. Renal impairment: In patients with mildly impaired renal function (creatinine clearance 60-89 ml/min) therapy should start at 50 mg total daily dose. Contraindicated in patients with moderate to severe renal dysfunction (creatinine clearance ≤ 59 ml/min). Paediatric population: Should not be used in children and adolescents as no studies have been performed. The tablet should be swallowed with a glass of water. For acute pain administration is recommended at least 30 minutes before meals.
Contraindications: Hypersensitivity to the active substance, or to any other NSAID, or to any of the excipients. Patients in whom substances with a similar action precipitate attacks of asthma, bronchospasm, acute rhinitis, or cause nasal polyps, urticarial or angioneurotic oedema. Known photoallergic or phototoxic reactions during treatment with ketoprofen or fibrates. Patients with history of gastrointestinal bleeding or perforation, related to previous NSAID therapy. Patients with active peptic ulcer/gastrointestinal haemorrhage or any history of gastrointestinal bleeding, ulceration or perforation. Chronic dyspepsia. Patients with other active bleedings or bleeding disorders. Crohn's disease or ulcerative colitis. Severe heart failure. Moderate to severe renal dysfunction (creatinine clearance ≤ 59 ml/min). Impaired hepatic function (Child-Pugh score 10-15). Haemorrhagic diathesis and other coagulation disorders. Severe dehydration. Third trimester of pregnancy and lactation.
Warnings and Precautions: Use with caution in patients with a history of allergic conditions. Concomitant use with other NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided. Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms. Gastrointestinal safety: If gastrointestinal bleeding or ulceration occurs during treatment, treatment should be withdrawn. The risk of gastrointestinal bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer and in the elderly. Caution should be advised in those patients receiving concomitant medications such as corticosteroids, anticoagulants, SSRIs or anti-platelet agents. Renal safety: Caution should be exercised in patients with impairment of renal functions. Liver safety: Caution should be exercised in patients with impairment of hepatic functions. Cardiovascular and cerebrovascular safety: Appropriate monitoring and advice are required for patients with a history of hypertension and/or mild to moderate heart failure. Special caution should be exercised in patients with a history of cardiac disease. Skin reactions: Keral should be discontinued at the first sign of skin rash, mucosal lesions, or any other sign of hypersensitivity. Caution is advised with congenital disorder of porphyrin metabolism, dehydration and directly after surgery. Avoid in patients with varicella.
Interactions: Avoid with other NSAIDs (including cyclooxygenase -2 selective inhibitors) and high doses of salicylates (≥ 3 g/day), anticoagulants, corticosteroids, lithium, methotrexate (15 mg/week or more), hydantoines and sulphonamides. Precautions are advised with diuretics, ACE inhibitors, antibacterial aminoglycosides, angiotensin II receptor antagonists, methotrexate (less than 15 mg/week), pentoxyfilline, zidovudine, sulfonylureas. Caution is advised when co-administered with beta-blockers, cyclosporine, tacrolimus, thrombolytics, anti-platelet agents, SSRIs, probenecid, cardiac glycosides, mifepristone, quinolone antibiotics, tenofovir, deferasirox and pemetrexed.
Pregnancy and lactation: Contraindicated during third trimester of pregnancy and during lactation.
Side-effects: Common (≥ 1/100 to < 1/10): nausea and/or vomiting, abdominal pain, diarrhoea and dyspepsia. Uncommon (≥ 1/1000 to < 1/100): Insomnia, anxiety, headache, dizziness, somnolence, vertigo, palpitations, flushing, gastritis, constipation, dry mouth, flatulence, rash, fatigue, pain, asthenia, rigors, malaise. Rare (≥ 1/10,000 to < 1/1,000): Laryngeal oedema, anorexia, paraesthesia, syncope,

hypertension, bradypnoea, peptic ulcer, peptic ulcer haemorrhage or peptic ulcer perforation, hepatocellular injury, urticarial, acne, sweating increased, back pain, acute renal failure, polyuria, menstrual disorder, prostatic disorder, peripheral oedema, liver function test abnormal. Very rare (<1/10,000): Neutropenia, thrombocytopenia, anaphylactic reaction, including anaphylactic shock, blurred vision, tinnitus, tachycardia, hypotension, bronchospasm, dyspnoea, pancreatitis, Stevens Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), angioedema, facial oedema, photosensitivity, reaction, pruritus, nephritis or nephrotic syndrome.

Package quantities and price: 20 tablets £3.67. 50 tablets £9.18.

Legal category: POM.

Marketing Authorisation Holder: Menarini International O.L.S.A.

Marketing authorisation numbers: PL 16239/0007

Marketed by: A. Menarini Farmaceutica Internazionale SRL.

Further information is available on request to A. Menarini Farmaceutica Internazionale SRL, Menarini House, Mercury Park, Wycombe Lane, Wooburn Green, Buckinghamshire, HP10 0HH, UK or may be found in the SmPC.

Last updated: July 2021

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to A. Menarini Farmaceutica Internazionale SRL. Phone no. 0800 085 8678 or email: menarini@medinformation.co.uk