CODAL-SYNTO

Relief from pain and inflammation

Oloxicam®

Meloxicam

OLOXICAM® 7.5mg tablets • **OLOXICAM®** 15mg tablets

Summary of SPC for Oloxicam®

Trade Name of the Medicinal Product:	Oloxicam®
Qualitative and Quantitative Composition:	Each tablet contains 7.5 mg or 15 mg of meloxicam.
Therapeutic indications:	Meloxicam is indicated for the short term symptomatic therapy of acute exacerbations of osteoarthritis, long term symptomatic treatment of rheumatoid arthritis (chronic polyarthritis), and the symptomatic therapy of ankylosing spondylitis.
Posology and Method of Administration:	Acute exacerbations of osteoarthritis: The recommended dose is 7.5 mg a day. If necessary, and depending upon the severity of symptoms, dosage may be increased to 15 mg daily. Rheumatoid arthritis & Ankylosing spondylitis: The recommended dose is 15 mg a day. According to the therapeutic response the dose may be reduced to 7.5mg a day. Renal impairment: Patients with severe renal failure undergoing dialysis should not exceed a dose of 7.5mg a day. Elderly & patients with increased risks for adverse reaction: The recommended dose for long term treatment is 7.5mg a day. Children: The safety and efficacy of meloxicam have not been established in children under the age of sixteen years.
Contra-indications:	Hypersensitivity to meloxicam or to one of the excipients or hypersensitivity to substances with a similar action, e.g. NSAIDs, aspirin; Patients who have developed signs of asthma, nasal polyps, angioneurotic oedema, urticaria or any other hypersensitivity reaction following the administration of any NSAID or aspirin; History of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy; Active or history of recurrent peptic ulcer/haemorrhage; Severe hepatic impairment; Non-dialysed severe renal failure; Gastrointestinal bleeding, cerebrovascular bleeding or other bleeding disorders; Severe heart failure; Last trimester of pregnancy and lactation. Non-dialysed severe renal failure; Gastrointestinal bleeding, history of cerebrovascular bleeding or other bleeding disorders; Severe heart failure; Children and adolescents aged under 16 years.
Special Warnings and Precautions for Use:	Patients with a history of oesophagitis, gastritis, peptic ulcer, gastrointestinal toxicity, ulcerative colitis, Crohn's disease; The possible occurrence of severe skin reactions and serious life threatening hypersensitivity reactions; Occasional increases in serum transaminase levels, increases in serum bilirubin or other liver function parameters, as well as increases in serum creatinine and blood urea nitrogen as well as other laboratory disturbances; Patients with risk factors for cardiovascular disease; Renal and Hepatic failure; Elderly; Meloxicam, as any other NSAID, may mask symptoms of an underlying infectious disease. The use of meloxicam, as with any drug known to inhibit cyclooxygenase/prostaglandin synthesis, may impair fertility and is not recommended in women attempting to conceive.
Interactions with other Medicaments and other forms of Interaction:	Other NSAIDs, including salicylates; Corticosteroids; Lithium; Anti-coagulants; Methotrexate; Cyclosporin; Diuretics, ACEIs and angiotensin II receptor antagonists; Other antihypertensive drugs (e.g. Beta-blockers); Intrauterine devices; Thrombolytics and antiplatelet drugs; SSRIs; Cholestyramine; Elderly patients, and those with even slight renal impairment.
Undesirable Effects:	Anaemia, disturbances of blood count, isolated cases of agranulocytosis; Anaphylactic / anaphylactoid reactions; Mood disorders, insomnia and nightmares; Light-headedness, headache, vertigo, tinnitus, drowsiness, confusion, visual disturbances including blurred vision; Palpitations, oedema, hypertension, cardiac failure, small increased risk of arterial thrombotic events, increase in blood pressure, flushes; Onset of asthma attacks; Dyspepsia, nausea, vomiting symptoms, abdominal pain, constipation, flatulence, diarrhea, gastrointestinal bleeding, peptic ulcers, oesophagitis, stomatitis, gastrointestinal perforation, gastritis, colitis, peptic ulcers; Transitory disturbance of liver function test, hepatitis; Pruritus, rash, urticaria, Stevens - Johnson syndrome, toxic epidermal necrolysis, angioedema, bullous reactions such as erythema multiforme, photosensitivity reactions; Disturbances of laboratory tests investigating renal function, sodium and water retention, hyperkalaemia, acute functional renal failure in patients with risk factors, isolated cases of interstitial nephritis, acute tubular necrosis, nephritic syndrome and papillary necrosis.
	MAH: Codal Synto Ltd.