

Malta, 20 July 2007
Circular No. P08/2007

Dear Healthcare Professional,

Re: Benefit-Risk Profile of Systemic Piroxicam

Following the recent finalisation of an Article 31 Referral initiated by the European Commission to establish the benefit-risk profile of systemic piroxicam, the Committee for Medicinal Products for Human Use (CHMP) has concluded that it should only be prescribed for osteoarthritis, rheumatoid arthritis and ankylosing spondylitis, by prescribers with experience in the treatment of patients with inflammatory or degenerative rheumatic diseases, at the lowest dose and for the shortest duration of time. Furthermore, the CHMP has recommended new contraindications and strengthened warnings for piroxicam. The outcome of this Referral has been made public in a [press release](#) and [Q & A document](#) by the EMEA. Further to this, the European Commission will shortly publish a Decision which is legally binding in all Member States and to be implemented by all Marketing Authorisation Holders holding a license for piroxicam-containing systemic medicinal products.