Prescribing Information

Myopridin tablets containing pridinol mesilate. Consult Summary of Product Characteristics before prescribing. For the treatment of central and peripheral muscle spasms: lumbar pain, torticollis, general muscle pain, in adults. **Dosage and administration** 1.5–3 mg pridinol 3 times daily. The duration of administration is decided by the treating doctor. Administration is independent of meals, with the onset of the effect being faster when taken before meals. Tablets should be taken with sufficient fluid (e.g. 1 glass of water) and not chewed. **Contraindications** Hypersensitivity to the active substance or to any of the excipients. glaucoma, prostate hypertrophy, syndrome with urinary retention, gastrointestinal obstructions, arrhythmia, first trimester of pregnancy. Special warnings and precautions Use with caution in the elderly, and in patients with severe renal and/or hepatic insufficiency, because higher and/or longer-lasting blood levels must be expected. In patients who suffer from hypotension, the risk of circulatory problems (fainting) may be increased. Myopridin contains lactose. Patients with the rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicinal product. Interaction with other medicinal products Myopridin potentiates the effect of anticholinergics such as atropine. Pregnancy and breastfeeding Myopridin is contraindicated during the first trimester of pregnancy and should be avoided during breastfeeding. Myopridin may only be used later in pregnancy after careful consideration, under medical supervision and only if absolutely necessary. Side effects The following adverse effects may occur, particularly during concomitant administration with other anticholinergic medicinal products: dry mouth, thirst, transient visual disorder (mydriasis, difficulties with accommodation, photosensitivity, slight increase in intraocular pressure), redness and dryness of the skin, bradycardia followed by tachycardia, micturition disorders. constipation and, very rarely, vomiting, dizziness and unsteady gait. Other side effects occur in fewer than 1 in 100 patients. Prescribers should consult the Summary of Product Characteristics in relation to the treatment of overdose and for details of other side effects. Effects on ability to drive and use machines Owing to potential anticholinergic effects on eyesight, greater caution is advised when driving vehicles and operating machines.

Presentation and Basic NHS Cost: Presented as a white round tablet diameter 9 mm with a score on one side. May be divided into equal doses. 3 mg x 20 tablets (£5.36) 3 mg x 100 tablets (£26.16)

Marketing Authorisation Numbers: PL 49452/0010

Legal Category POM Date of Last Revision: May 2020

For further information, please contact: Mibe Pharma UK Ltd, 6th Floor, 4 Coleman

Street, London EC2R 5AR, United Kingdom

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 Medical Information on 01271 314320

UK/MYO/20/001a

Date of preparation: Oct 2020