



Rapid onset of antidiarrhoeal action

Miraton[®]

Loperamide Hcl



CODAL-SYNTO

MIRATON[®] 2mg capsules

Summary of SPC for Miraton®

Name of the Medicinal Product:	Miraton®
Qualitative and Quantitative Composition:	Each capsule contains loperamide hydrochloride 2mg.
Pharmaceutical form:	Capsules
Therapeutic Indications	Symptomatic treatment of acute diarrhoea of any aetiology, including acute exacerbation of chronic diarrhoea, for a period of up to five days in adults and children over eight years of age; Symptomatic treatment of chronic diarrhoea in adults.
Posology and Method of Administration:	<p>Acute diarrhoea: Adults and children over 12 years: Two capsules initially, and one capsule after each loose stool. The usual dose is three to four capsules per day. The total daily dose should not exceed eight capsules. Children 9-12 years: One capsule four times daily until diarrhoea is controlled (up to 5 days). This dose should not be exceeded. Loperamide is not recommended for children under eight years old.</p> <p>Chronic diarrhoea: The dose required for control may differ from patient to patient. A starting dose of between two and four capsules per day in divided doses should be used, depending upon the severity of the condition. If necessary, the dose can be adjusted up to a maximum of eight capsules daily in divided doses. Once the maintenance dose is established, daily dose may be administered on a twice per day dosing regime.</p>
Contra-indications:	Hypersensitivity; Children less than 8 years of age; When inhibition of peristalsis is to be avoided due to the possible risk of significant sequelae including ileus, megacolon and toxic megacolon in particular; When ileus or constipation are present or when abdominal distension develops particularly in severely dehydrated children; Patients with acute ulcerative colitis, bacterial enterocolitis, pseudomembranous colitis associated with the use of broad-spectrum antibiotics, Miraton® should not be used alone in acute dysentery.
Special Warnings and Precautions for Use:	Prevention or reversal of fluid and electrolyte depletion particularly in young children and elderly; Should not be used for extended periods until the underlying cause of the diarrhoea has been investigated. Impaired hepatic function; Patients with AIDS; Miraton® contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.
Interactions with other Medicaments and other forms of Interaction:	Quinidine, Ritonavir; Oral desmopressin.
Pregnancy and Lactation:	Pregnancy and lactation: Not recommended.
Effects on Ability to Drive and Use Machines:	Caution is advisable when driving a car or operating machinery.
Undesirable Effects:	Allergic reactions, severe hypersensitivity reactions such as anaphylactic shock and anaphylactoid reactions; Drowsiness; Loss of consciousness, depressed level of consciousness, dizziness; Abdominal pain, ileus, abdominal distension, nausea, constipation, vomiting, megacolon including toxic megacolon, flatulence, dyspepsia; Rash, urticaria, pruritus, angioedema, bullous eruptions including Stevens-Johnson Syndrome, erythema multiforme, toxic epidermal necrolysis; Urinary retention.
Date of Revision of the Text:	11/2014

MAH: Codal-Synto Ltd.

