Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard

Adverse events should also be reported to McNeil Products Limited on 0808 238 9999.

IMODIUM® Original 2mg Capsules (loperamide) Product Information:

Presentation:
Opaque green cap and grey body, hard gelatin capsule imprinted with 'Imodium' on cap and 'Janssen' on body containing loperamide hydrochloride 2mg.

Uses:
Symptomatic treatment of acute diarrhoea in adults and children aged 12 years and over. For the symptomatic treatment of acute episodes of diarrhoea associated with irritable bowel syndrome in adults following initial diagnosis by a doctor.

Dosage:
Capsules should be taken with liquid. Acute Diarrhoea: *Adults and children over 12 years old:* 2 capsules initially followed by 1 capsule after every loose stool. The maximum daily dose should not exceed 6 capsules. Symptomatic treatment of acute episodes of diarrhoea associated with irritable bowel syndrome (IBS) in adults aged 18 years and over: Two capsules to be taken initially, followed by 1 capsule after every loose stool, or as previously advised by your doctor. The maximum daily dose should not exceed 6 capsules.

Contraindications:
Hypersensitivity to loperamide or any excipient. Children under 12 years of age. Acute dysentery, characterized by blood in stools and high fever. Acute ulcerative colitis. Bacterial enterocolitis caused by invasive organisms. Pseudomembranous colitis associated with broad spectrum antibiotics. Conditions when inhibition of peristalsis is to be avoided due to the possible risk of ileus, megacolon or toxic megacolon. Discontinue promptly when ileus, constipation or abdominal distension develop.

Precautions:
Treatment with IMODIUM® capsules is symptomatic; give specific treatment when appropriate. The priority in acute diarrhoea is the prevention or reversal of fluid and electrolyte depletion, particularly in young children and in frail and elderly patients. Use of IMODIUM® capsules does not preclude the administration of appropriate fluid and electrolyte replacement therapy. Since persistent diarrhoea can be an indicator of potentially more serious conditions, IMODIUM® capsules should not be used for prolonged periods until the underlying cause of the diarrhoea has been investigated. If symptoms persist for more than 48 hours, consult a doctor. Patients with AIDS should stop therapy with IMODIUM® capsules if abdominal distension develops. Use with caution in hepatic impairment. Patients with galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine as it

contains lactose. If IMODIUM® capsules are being used to control episodes of diarrhoea associated with irritable bowel syndrome, consult a doctor if clinical improvement is not seen within 48 hours, for any changes in the pattern of symptoms or if there is a need for continuous treatment of more than 2 weeks. Consult a doctor if patients have recently travelled abroad, are vomiting, having difficulty or pain passing urine, or have a loss of appetite. Cardiac events have been reported in association with overdose. Some cases with extremely high doses had a fatal outcome. Loss of consciousness, depressed level of consciousness, tiredness, dizziness, or drowsiness may occur when diarrhoea is treated with this medicine. Therefore, it is advisable to use caution when driving a car or operating machinery. Cardiac events including QT interval and QRS complex prolongation and torsades de pointes have been reported in association with overdose. Overdose can unmask existing Brugada syndrome. Patients should not exceed the recommended dose and/or the recommended duration of treatment. Caution is needed in patients with a history of drug abuse. Abuse and misuse of loperamide, has been described. Upon cessation, cases of drug withdrawal syndrome have been observed in individuals abusing, misusing, or intentionally overdosing with excessively large doses of loperamide. Loperamide is an opioid with low bioavailability and limited potential to penetrate the blood brain barrier at therapeutic doses. However, addiction is observed with opioids as a class.

Pregnancy and lactation:
Not recommended.

Side Effects:
Common: headache, constipation, nausea and flatulence.
Uncommon: dizziness, somnolence, abdominal pain, abdominal discomfort, dry mouth, abdominal pain upper, vomiting, dyspepsia and rash.
Rare: hypersensitivity reaction, anaphylactic reaction (including anaphylactic shock), anaphylactoid reaction, loss of consciousness, stupor, depressed level of consciousness, hypertonia, coordination abnormality, miosis, ileus (including paralytic ileus), megacolon (including toxic megacolon), abdominal distension, bullous eruption (including Stevens-Johnson syndrome, toxic epidermal necrolysis and erythema multiforme), angioedema; urticaria; pruritus; urinary retention; fatigue.
Not known: acute pancreatitis.
Please refer to Summary of Product Characteristics for detailed information.

RRP (ex-VAT): 6 capsules, £3.48
Legal Category: GSL
PL Holder: McNeil Products Ltd., 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG
PL Number: 15513/0310
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