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

Adverse events should also be reported to McNeil Products Limited on 01344 864 042.

IMODIUM® Instant Melts (loperamide) Product Information:

Presentation:
White/off-white, circular, orodispersible tablet containing loperamide hydrochloride 2mg. Excipients with known effect: each tablet contains 0.750 micrograms of Aspartame (E951) which is equivalent to 0.055 mg/mg and it contains less than 0.00066mg of benzyl alcohol. The Mint flavouring contains traces of Sulphites.

Indications:
For the symptomatic treatment of acute diarrhoea and acute episodes of diarrhoea associated with Irritable Bowel Syndrome diagnosed by a doctor.

Dosage and Administration:
Acute Diarrhoea: *Adults and children over 12 years old:* 2 tablets initially followed by 1 tablet after every loose stool. Total daily dose should not exceed 6 tablets. Symptomatic treatment of acute episodes of diarrhoea associated with Irritable Bowel Syndrome in adults: 2 tablets initially followed by 1 tablet after every loose stool, or as previously medically advised. Total daily dose should not exceed 6 tablets. Method of administration: Allow the tablet to disintegrate on the tongue and swallow; no liquid is needed.

Contraindications:
Hypersensitivity to loperamide or any excipient. Children under 12 years of age. Acute dysentery, characterised 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® Instant Melts 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® Instant Melts 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® Instant Melts 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 Instant Melts if abdominal distension develops. Contains maltodextrin which contains glucose, patients with rare glucose-galactose malabsorption should not take this medicine. Contains benzyl alcohol, which may cause allergic

reactions. Use with caution in hepatic or renal impairment, or in patients who are pregnant or breast feeding, because of the risk of accumulation and toxicity (metabolic acidosis). If IMODIUM® Instant Melts are being used tocontrol 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. Patients should consult a doctor if aged 40 or over where it is some time since their last IBS attack or if symptoms differ to previous episodes; in cases of severe constipation; weight loss or loss of appetite; pain passing urine; blood is present in stools; episode after recent travel abroad. 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 loperamide. 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: The most commonly reported adverse drug reactions in clinical trials in acute diarrhoea were: constipation (2.7%), flatulence (1.7%), headache (1.2%) and nausea (1.1%).

Uncommon: dizziness; somnolence; abdominal pain or discomfort; dry mouth; vomiting; dyspepsia; rash.

Rare: hypersensitivity reaction; anaphylactic reaction (including anaphylactic shock); anaphylactoid reaction; loss of consciousness; stupor; depressed level of consciousness; hypertonia; coordination abnormality; miosis; ileus (and paralytic ileus); megacolon (and toxic megacolon); glossodynia; abdominal distension; bullous eruption (including Stevens-Johnson syndrome, toxic epidermal necrolysis and erythema multiforme); angioedema; urticaria; pruritis; urinary retention; fatigue.

Not Known: Acute pancreatitis.

RRP (ex-VAT): 12 tablets, £7.03, 18 tablets £9.68

Legal Category: P

PL Holder: McNeil Products Ltd., 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG

PL Number: 15513/0346

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