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 0808 238 9999.

IMODIUM® Instant Melts (Loperamide Hydrochloride) Product Information:

Presentation:
White to 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 mint flavour, which contains less than 0.00066mg of benzyl alcohol, less than 0.24 mg of maltodextrin (which contains glucose), and 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 in adults and children over 12 years old: two tablets to be taken initially followed by one tablet after every loose stool. The total daily dose should not exceed 6 tablets.
Symptomatic treatment of acute episodes of diarrhoea associated with irritable bowel syndrome in adults: two tablets initially followed by one tablet after every loose stool, or as previously medically advised. The 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:
IMODIUM® Instant Melts is contraindicated in children under 12 years of age, in individuals with hypersensitivity to loperamide hydrochloride or any of the excipients. This product should not be used in the following conditions: acute dysentery, which is characterised by blood in stools and high fever, acute ulcerative colitis, bacterial enterocolitis caused by invasive organisms such as *Salmonella*, *Shigella*, and *Campylobacter*, and pseudomembranous colitis associated with broad spectrum antibiotics. Do not use this product in conditions wherein the inhibition of peristalsis must be avoided, due to the possible risk of ileus, megacolon, or toxic megacolon. Discontinue this product immediately 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. 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). Patients with AIDS should stop therapy with IMODIUM® Instant Melts if abdominal distension develops. This product contains maltodextrin which contains glucose; therefore, patients with rare glucose-galactose malabsorption should not take this medicine. It also contains benzyl alcohol, which may cause allergic reactions. If IMODIUM® Instant Melts 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. 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, presence of blood in stools, and if the episode occurs 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:

This product is not recommended in pregnant and lactating women.

Side Effects:

Common: constipation, flatulence, headache, nausea.

Uncommon: dizziness, somnolence, abdominal pain, abdominal discomfort, dry mouth, abdominal pain upper, vomiting, dyspepsia, rash.

Rare: hypersensitivity reaction, anaphylactic reaction (including anaphylactic shock), anaphylactoid reaction, loss of consciousness, stupor, depressed level of consciousnes s, 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, pruritus, 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
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