

Product Information for IMODIUM® Classic 2mg Capsules (Loperamide), IMODIUM® Dual Action Relief Tablets and IMODIUM® Instant Melts (loperamide)

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® Classic 2mg Capsules (Loperamide) Product Information

Presentation:

Opaque green cap and grey body, hard gelatin capsule containing Loperamide hydrochloride 2mg.

Uses:

Symptomatic treatment of acute diarrhoea in adults and children aged 12 years and over. Symptomatic treatment of acute episodes of diarrhoea associated with Irritable Bowel Syndrome in adults aged 18 years and over following initial diagnosis by a doctor.

Dosage:

Acute Diarrhoea: *Adults and children 12 years and over:* 2 capsules initially followed by 1 capsule after every loose stool. Total daily dose should not exceed 6 capsules. Symptomatic treatment of acute episodes of diarrhoea associated with Irritable Bowel Syndrome in adults: *Adults 18 years and over:* 2 capsules to be taken initially, followed by 1 capsule after every loose stool, or as previously advised by your doctor. Total daily dose should not exceed 6 capsules.

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® Classic 2mg 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® Classic 2mg 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® Classic 2mg 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® Classic 2mg Capsules if abdominal distension develops. Use with

caution in hepatic impairment. If IMODIUM® Classic 2mg 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. If the pattern of symptoms changes or if repeated episodes of diarrhoea continue for more than 2 weeks consult doctor. 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; pruritis; urinary retention; fatigue.

Not Known: Acute pancreatitis.

RRP (ex VAT): 12's: £6.08

Legal Category: P

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

PL Number(s): 15513/0309

Date of Preparation: 12 January 2023

IMODIUM® Dual Action Relief Tablets (Formerly IMODIUM® Plus Caplets) (loperamide hydrochloride)

Product Information

Presentation:

White, capsule-shaped tablet containing loperamide hydrochloride 2mg and simeticone equivalent to 125mg dimeticone.

Indications:

Symptomatic treatment of acute diarrhoea in adults and adolescents over 12 years when acute diarrhoea is associated with gas-related abdominal discomfort including bloating, cramping or flatulence.

Dosage and Administration:

Swallow the correct number of tablets whole with a drink of water. *Adults over 18 years:* Take 2 tablets initially, followed by 1 tablet after every loose stool. *Adolescents aged 12-18 years:* Take 1 tablet initially followed by 1 tablet after each loose stool. Not more than 4 tablets should be taken in 24 hours, limited to no more than 2 days.

Contraindications:

Not to be used in children under 12 years of age, or patients with: hypersensitivity to loperamide or simeticone or to any of the excipients listed in SPC section 6.1; acute dysentery (characterised by blood in stool and high fever); acute ulcerative colitis; pseudomembranous colitis associated with broad spectrum antibiotics; bacterial enterocolitis caused by invasive organisms. Must not be used when inhibition of peristalsis is to be avoided. Therapy must be discontinued if constipation, ileus and/or abdominal distension develop.

Precautions:

Treatment of diarrhoea with loperamide-simeticone is only symptomatic; give specific treatment when appropriate. Upon cessation, cases of drug withdrawal syndrome have been observed in individuals abusing, misusing, or intentionally overdosing with excessively large doses of loperamide. In patients with severe diarrhoea, attention should be paid to appropriate fluid and electrolyte replacement. If clinical improvement is not seen within 48 hours, stop treatment and consult a doctor. Patients with AIDS should stop therapy if abdominal distension develops. Use under medical supervision in patients with hepatic dysfunction. Cardiac events including QT interval and QRS complex prolongation and torsades de pointes have been reported in association with overdose. Some cases had a fatal outcome. Overdose can unmask existing Brugada syndrome. Imodium Plus contains benzyl alcohol (less than 0.026 mg per tablet), which may cause allergic reactions. Imodium Plus must be used with caution in patients with renal or hepatic impairment, or in patients who are pregnant or breast-feeding, because of the risk of accumulation and toxicity (metabolic acidosis). This medicine contains maltodextrin (less than 4.4 mg per tablet) which contains glucose. Patients with rare glucose-galactose malabsorption should not take this medicine.

Pregnancy and lactation:

Not recommended.

Fertility:

Effect has not been evaluated.

Ability to drive:

Imodium Dual Action Relief has no or negligible influence on the ability to drive and use machines. However, tiredness, dizziness and drowsiness may occur in the setting of diarrheal syndromes treated with loperamide HCl. Therefore, it is advisable to use caution when driving a car or operating machinery.

Side Effects:

The most commonly reported adverse drug reactions in clinical trials were: dysgeusia (2.6%) and nausea (1.6%). Additionally, adverse drug reactions reported with the use of loperamide-simeticone from either clinical trial or post-marketing experience and with the use of loperamide HCl are:

Common:

Headache.

Uncommon:

Somnolence, dizziness, abdominal pain, abdominal discomfort, abdominal pain upper, vomiting, constipation, abdominal distension, dyspepsia, flatulence, dry mouth, rash and asthenia.

Rare:

Hypersensitivity reaction, anaphylactic reaction (including anaphylactic shock), anaphylactoid reaction, loss of consciousness, depressed level of consciousness, stupor, hypertonia, coordination abnormality, miosis, ileus (including paralytic ileus), megacolon (including toxic megacolon), bullous eruption (including Stevens-Johnson syndrome, toxic epidermal necrolysis and erythema multiforme), angioedema, urticaria, pruritus, urinary retention and fatigue.

Not known:

Acute pancreatitis.

RRP (ex-VAT): 12 tablets, £6.58

Legal Category: P

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

PL Number: 15513/0342

Date of Preparation: 04 April 2023.

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 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; 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

Date of Preparation: 09 January 2024