

Product Information for IMODIUM® Original 2mg Capsules (loperamide), IMODIUM® Instants (loperamide) and IMODIUM® IBS Relief 2mg Capsules Soft, (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 01344 864 042.

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; pruritis; urinary retention; fatigue.

Not Known: Acute pancreatitis.

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

Date of Prep: 12 Jan 2023

IMODIUM® Instants (loperamide) Product Information:

Presentation:

White/off-white, circular, orodispersible tablet containing loperamide hydrochloride 2mg. Excipients with known effect: Each tablet contains 0.750 mg 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.

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 over 12 years old:* Two 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 aged 18 years and over: Two tablets to be taken initially, followed by 1 tablet after every loose stool, or as previously advised by your doctor. 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® Instants 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® Instants 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® Instants 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® Instants 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. Some cases with extremely high doses had a fatal outcome. 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: 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): 6 tablets £4.60; 12 tablets £7.03

Legal Category: GSL

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

PL Number: 15513/0345

Date of Preparation: 09 January 2024

IMODIUM[®] IBS Relief 2mg Capsules Soft, Loperamide, Product Information:

Presentation:

Clear blue, oval, soft gelatin capsule containing Loperamide hydrochloride 2mg. Excipient with known effect: each capsule contains 115.31 mg Propylene Glycol which is equivalent to 0.65 mg/mg, also contains 0.06 micrograms of soya lecithin.

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 over 12 years old:* 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. Patients with allergies to soya or peanuts. 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® IBS Relief 2mg Capsules Soft 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® IBS Relief 2mg Capsules Soft 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® IBS Relief 2mg Capsules Soft 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® IBS Relief 2mg Capsules Soft if abdominal distension develops. Use with caution in hepatic impairment. If IMODIUM® IBS Relief 2mg Capsules Soft 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): 6's: £4.08

Legal Category: GSL

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

PL Number: 15513/0367

Date of Preparation: 12 Jan 2023