Imodium™ INSTANTS

loperamide

1. Composition

Loperamide hydrochloride 2mg per tablet. For ingredients see Section 9 ▸

2. Pharmaceutical Form

Imodium Instants are white to off-white, orodispersible (dissolve in the mouth),circular, freeze-dried tablets

3. Indications

This medicine is used to treat sudden short-lived (acute) attacks of diarrhoea in adults and children aged 12 years and over. It can also be used to treat diarrhoea associated with Irritable Bowel Syndrome (IBS) in adults aged 18 years and over after your doctor has diagnosed you are suffering from this condition.

Now read this whole leaflet carefully before you use this medicine.

Keep the leaflet: you might need it again.

4. Dosage:

Check the table below to see how many tablets to take.

- Peel back the lid and tip the tablet out. Do not push the tablet through the lid.

Place the correct number of tablets on the tongue. The tablets dissolve quickly, so you don't need water to swallow them. Do not chew.

For oral use only.

Do not use more than the stated dose shown in the table.

Adults and children 12 years and over

To treat sudden short-lived (acute) diarrhoea:

Age:	Dose:
Adults and children aged 12 years and over	Take 2 tablets (4mg) initially, followed by 1tablet (2mg) after each loose stool

- The usual daily dose is 3-4 tablets (6mg-8mg)
- If symptoms persist for more than 24 hours talk to your doctor
- Do not take more than 8 tablets (16mg) in any 24 hour period

Adults aged 18 years and over

To treat Diarrhoea associated with Irritable Bowel Syndrome already diagnosed by a doctor:

Age:	Dose:
Adults aged 18 years and over	Take 2 tablets (4mg) initially. Further loose stools may be controlled by taking 1or 2 tablets depending on the severity of your symptoms.

- The usual daily dose is 2-4 tablets (4mg-8mg)
- Do not take more than 8 tablets in any 24 hour period
- If your symptoms change, or if your diarrhoea persists for more than 24 hours, talk to your doctor.

- **This medicine is not recommended for children under 12 years old.**

Elderly:

- No dose adjustment is required for the elderly.

Renal impairment:

- No dose adjustment is required for patients with renal impairment.

Hepatic impairment:

- Although no pharmacokinetic data are available in patients with hepatic impairment, Imodium Instants should be used with caution in such patients because of reduced first pass metabolism.

Method of Administration

- Oral Use. Allow tablet to disintegrate on the tongue and swallow the medication. No need to use water.

5. Contraindications

Do not take this medicine…

- If you have a known hypersensitivity to loperamide hydrochloride or to any of the ingredients.
- If it is for a child **under 12 years old.**
- If you have a flare up of an **inflammatory bowel** condition like **ulcerative colitis**
- If you have **acute dysentery**, the symptoms of which may include **blood in your stools** and a **high temperature.**
- If you have **bacterial enterocolitis** caused by invasive organisms including Salmonella, Shigella and Campylobacter.
- If you have **pseudomembranous colitis** associated with the use of broad-spectrum antibiotics.

If any of these apply to you, **get advice from a doctor or pharmacist without taking Imodium Instants.**

Imodium Instants must not be used when inhibition of peristalsis is to be avoided due to the possible risk of significant sequelae including ileus, megacolon and toxic megacolon. Imodium Instants must be discontinued promptly when ileus, constipation or abdominal distension develop.

6. Special Warnings and precautions for use

Imodium Instants only treat the symptoms of diarrhoea. When you have diarrhoea, your body can lose large amounts of fluids and salts. You will need to replace the fluid by drinking more liquid than usual. This is particularly important in young children and in frail and elderly patients with acute diarrhoea. Ask your pharmacist about special powders **(known as oral rehydration therapy)** which replace fluids and salts lost during diarrhoea.

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.

Talk to your doctor or pharmacist…

- If your acute diarrhoea lasts for more than 24 hours, stop taking the tablets and contact your doctor
- If you have **AIDS** and **you have abdominal distension** (stomach becomes swollen),stop taking the tablets immediately and contact your doctor. There have been isolated reports of obstipation with an increased risk for toxic megacolon in AIDS patients with infectious colitis from both viral and bacterial pathogens treated with loperamide hydrochloride.
- If you suffer from hepatic impairment **(liver disease)**. Although no pharmacokinetic data are available in patients with hepatic impairment, Imodium Instants should be used with caution because of reduced first pass metabolism, as it may result in a relative overdose leading to CNS toxicity.
- You can use Imodium Instants for diarrhoea associated with IBS which has been diagnosed by your doctor. If your symptoms change or your diarrhoea lasts for **more than 2 weeks** you should talk to your doctor.

Interactions with other Medicinal products

- Non-clinical data have shown that loperamide is a P-glycoprotein substrate. Concomitant administration of loperamide (16 mg single dose) with quinidine, or ritonavir, which are both P-glycoprotein inhibitors, resulted in a 2 to 3-fold increase in loperamide plasma levels. The clinical relevance of this pharmacokinetic interaction with P-glycoprotein inhibitors, when loperamide is given at recommended dosages is unknown.
- The concomitant administration of loperamide (4 mg single dose) and itraconazole, an inhibitor of CYP3A4 and P-glycoprotein, resulted in a 3 to 4 fold increase in loperamide plasma concentrations. In the same study a CYP2C8 inhibitor, gemfibrozil, increased loperamide by approximately 2 fold. The combination of itraconazole and gemfibrozil resulted in a 4 fold increase in peak plasma levels of loperamide and a 13-fold increase in total plasma exposure. These increases were not associated with central nervous system (CNS) effects as measured by psychomotor tests (i.e. subjective drowsiness and the Digit Symbol Substitution Test).
- The concomitant administration of loperamide (16 mg single dose) and ketoconazole, an inhibitor of CYP3A4 and P-glycoprotein, resulted in a 5 fold increase in loperamide plasma concentrations. This increase was not associated with increased pharmacodynamic effects as measured by pupillometry.

Concomitant treatment with oral desmopressin resulted in a 3 fold increase of desmopressin plasma concentrations, presumably due to slower gastrointestinal motility.

- It is expected that drugs with similar pharmacological properties may potentiate loperamide's effect and that drugs that accelerate gastrointestinal transit may decrease its effect.

If you are pregnant or breast-feeding

Safety in human pregnancy has not been established. As with other drugs, it is not advisable to administer loperamide in pregnancy, especially during the first trimester. Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant, think you are pregnant or planning to become pregnant.

Do not take this medicine if you are breast-feeding as small amounts may get into your milk. Talk to your doctor about a suitable treatment.

Effects on ability to drive and use machines

- Loss of consciousness, depressed level of consciousness, tiredness, dizziness, or drowsiness may occur when diarrhoea is treated with loperamide. Therefore it is advised to use caution when driving a car or operating machinery.

7. Possible side-effects

Imodium Instants can have side-effects, like all medicines, although these don't affect everyone and are usually mild.

The safety of loperamide HCl was evaluated in 2755 adults and children aged 12 years or above who participatedin 26 controlled and uncontrolled clinical trials of loperamide HCl used for the treatment of acute diarrhoea.

The most commonly reported (i.e. >1% incidence) adverse drug reactions (ADRs) in clinical trials with loperamide HCl in acute diarrhoea were: constipation (2.7%), flatulence (1.7%), headache (1.2%) and nausea (1.1%).'

Table 1 displays ADRs that have been reported with the use of loperamide HCl from either clinical trial (acute diarrhoea) or post marketing experience.

Table 1: Adverse Drug Reactions

System Organ Class	Indication		
	Common	Uncommon	Rare
	(≥1/100 to <1/10)	(≥1/1,000 to <1/100)	(≥1/10,000 to <1/1,000); and very rare (<1/10,000)
Immune System Disorders			Hypersensitivity reaction[a] Anaphylactic reaction (including Anaphylactic shock)[a] Anaphylactoid reaction[a]
Nervous System Disorders	Headache	Dizziness Somnolence[a]	Loss of consciousness[a] Stupor[a] Depressedlevel of consciousness[a] Hypertonia[a] Coordination abnormality[a]

System Organ Class	Indication		
	Common	Uncommon	Rare
Eye Disorders			Miosis[a]
Gastrointestinal Disorders	Constipation Nausea Flatulence	Abdominal pain Abdominal Discomfort Dry mouth Abdominal pain upper Vomiting Dyspepsia[a]	Ileus[a] (including paralytic ileus) Megacolon[a] (including toxic megacolon[b]) Glossodynia[a] Abdominal distension
Skin and Subcutaneous Tissue Disorders		Rash Angioedema[a]	Bullous eruption[a] (including Stevens-Johnson syndrome, Toxic epidermal necrolysis and Erythema multiforme) Urticaria[a] Pruritus[a]
Renal and Urinary Disorders			Urinary retention[a]
General Disorders and Administration Site Conditions			Fatigue[a]

a: Inclusion of this term is based on post-marketing reports for loperamide HCl. As the process for determining post marketing ADRs did not differentiate between chronic and acute indications or adults and children, the frequency is estimated from all clinical trials with loperamide HCl (acute and chronic), including trials in children 12 years (N=3683).
b: See section 6 Special Warnings and Special Precautions for use.

If you experience any side-effects not included in this leaflet or are not sure about anything, talk to your doctor or pharmacist.

Overdose:

Symptoms: In case of overdose (including relative overdose due to hepatic dysfunction), CNS depression (stupor, coordination abnormality, somnolence, miosis, muscular hypertonia and respiratory depression), constipation, urinary retention and ileus may occur. Children, and patients with hepatic dysfunction, may be more sensitive to CNS effects.

Treatment: If symptoms of overdose occur, naloxone can be given as an antidote. Since the duration of action of loperamide is longer than that of naloxone (1 to 3 hours), repeated treatment with naloxone might be indicated. Therefore, you should be monitored closely for at least 48 hours in order to detect any possible depression of the central nervous system.

8. Pharmacological Properties

- **Pharmacodynamic Properties**

ATC Code: A07DA

Loperamide binds to the opiate receptor in the gut wall, reducing propulsive peristalsis and increasing intestinal transit time. Loperamide increases the tone of the anal sphincter.

In a double blind randomised clinical trial in 56 patients with acute diarrhoea receiving loperamide, onset of anti-diarrhoeal action was observed within one hour following a single 4 mg dose. Clinical comparisons with other anti-diarrhoeal drugs confirmed this exceptionally rapid onset of action of loperamide.

- **Pharmacokinetic Properties**

The half-life of loperamide in man is 10.8 hours with a range of 9 -14 hours. Studies on distribution in rats show high affinity for the gut wall with preference for binding to the receptors in the longitudinal muscle layer. Loperamide is well absorbed from the gut, but is almost completely extracted and metabolised by the liver where it is conjugated and excreted via the bile. Due to its high affinity for the gut wall and its high first pass metabolism, very little loperamide reaches the systemic circulation.

- **Preclinical Safety Data**

Not Applicable

9. List of Ingredients

The active ingredient in Imodium Instants is: Loperamide hydrochloride 2 mg per tablet .

Other ingredients are: Gelatin, mannitol, aspartame, mint flavour and sodium hydrogen carbonate.

- **Incompatibilities**

Not Applicable

- **Shelf Life**

24 months

- **Storing this medicine**

Keep the product out of the reach and sight of children

Store in original package at or below 30 °C

Unless instructed otherwise, do not dispose of unused medicines by emptying them into your sink, toilet or storm drain.

- **Nature and Contents of Container**

All-aluminum blister packs of 6, 12, 18, and 24 tablets in printed cardboard cartons. Not all pack sizes may be marketed.

The all-aluminum blisters are made from paper, PET, aluminum, PVC and polyamide.

Product License holder:
McNeil Products Ltd, Foundation Park, Roxborough Way, Maidenhead, Berkshire, SL6 3UG, UK.

Manufacturer:
Catalent UK Swindon Zydis Limited, Frankland Road, Blagrove Swindon Wiltshire SN5 8RU, UK
Marketing Authorisation Number PL 15513/0346

Date of First Authorisation/Renewal of Authorisation 16/12/2008

This leaflet was partly revised July 2011
Imodium is a registered trade mark.
Mc Neil products Ltd.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctors' prescription, the method of use and the instructions of the pharmacist who sold the medicine.
- The doctor and pharmacist are experts in the use of medicines, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribe for you.
- Do not repeat the same prescription without consulting your doctor.

McNeil Products Ltd.

Council of Arab Health Ministers
Union of Arab Pharmacists

30x15cm

TOP