SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

LOPEZ (Loperamide Hydrochloride Capsules BP 2 mg)

2. Qualitative and quantitative composition

Each hard gelatin Capsule contains 2mg of Loperamide Hydrochloride BP

For full list of excipients, see section 6.1.

3. Pharmaceutical form

Capsule
A hard gelatin capsule size “2” having green colour cap and grey body containing white colour
powder.

4.ClinicalParticulars:

4.1 Therapeutic indications

For the symptomatic treatment of acute diarrhea of any etiology including acute exacerbations of chronic diarrhoea for periods of up to 5 days in adults and children over 9 years. For the symptomatic treatment of chronic diarrhoea in adults.

4.2 Posology and method of administration

Acute diarrhoea

Adults and children over 12 years

Two Capsules (4 mg) initially, followed by one Capsules (2 mg) after every loose stool. The usual dosage is 3-4 Capsules (6 mg-8 mg) per day. The maximum daily dose should not exceed
8 Capsules (16 mg).

Children 9 to 12 years

One Capsules (2 mg) four times daily until diarrhoea is controlled (up to 5 days). This dose should not be exceeded.

Further investigation into the cause of the diarrhoea should be considered if there is no improvement within two days of starting treatment with loperamide.

Chronic diarrhoea

Adults

Patients may need widely differing amounts of loperamide. The starting dose should be between two and four Capsulesper day in divided doses, depending on severity. If required, this dose can be adjusted according to result up to a maximum of eight Capsulesdaily.

Having established the patient's daily maintenance dose, loperamide may be administered on a twice daily regimen. Tolerance has not been observed and therefore subsequent dosage adjustment should be unnecessary.

Elderly

No dose adjustment is required for the elderly.

Renal impairment

No dose adjustment is required for patients with renal impairment

Method of administration
Oral

4.3 Contraindications
Loperamide is contraindicated in:
Patients with a known hypersensitivity to loperamide hydrochloride or to any of the excipients.
Children less than 9 years of age.
Loperamide should not be used as the primary therapy:
Patients with acute dysentery, which is characterized by blood in stools and high fever.
Patients with acute ulcerative colitis.
Patients with bacterial enterocolitis caused by invasive organisms including Salmonella, Shigella and Campylobacter.
Patients with pseudomembranous colitis associated with the use of broad-spectrum antibiotics.
Loperamide should 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. Loperamide must be discontinued promptly when constipation, abdominal distension or ileus develop.

4.4 Special warnings and precautions for use
Treatment of diarrhoea with loperamide is only symptomatic. Whenever an underlying etiology can be determined, specific treatment should be given when appropriate.
The priority in acute diarrhoea is the prevention or reversal of fluid and electrolyte depletion. This is particularly important in young children and in frail and elderly patients with acute diarrhoea. Use of loperamide hydrochloride does not preclude the administration of appropriate fluid and electrolyte replacement therapy.
Since persistent diarrhoea can be an indicator of potentially more serious conditions, loperamide hydrochloride should not be used for prolonged periods until the underlying cause of the diarrhoea has been investigated.

Loperamide hydrochloride must be used with caution when the hepatic function necessary for the drug's metabolism is defective (e.g. in cases of severe hepatic disturbance), as this might result in a relative overdose leading to CNS toxicity
Patients with AIDS treated with loperamide hydrochloride for diarrhoea should have therapy stopped at the earliest signs of abdominal distension. There have been isolated reports of toxic megacolon in AIDS patients with infectious colitis from both viral and bacterial pathogens treated with loperamide hydrochloride.
When no clinical change is observed in the acute diarrhoea within 48 hours, the administration of loperamide must be interrupted and the patient must be advised to consult his doctor. Treatment with Loperamide must be interrupted immediately when obstipation, abdominal distension or subileus develops

Cardiac events including QT prolongation and torsades de pointes have been reported in association with overdose. Some cases had a fatal outcome. Overdose can unmask existing Brugada syndrome. Patients should not exceed the recommended dose and/or the recommended duration of treatment.
Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine because it contains lactose.

4.5 Interaction with other medicinal products and other forms of interaction
Non-clinical data have shown that loperamide is a P-glycoprotein substrate. Furthermore, loperamide is mainly metabolized by CYP3A4 and CYP2C8.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 results of one published pharmacokinetic study suggested that the concomitant administration of loperamide with oral desmopressin may result in a 3-fold increase of desmopressin plasma concentrations although no clinical effects were reported.
Possible interactions may occur with drugs that delay intestinal peristalsis (for instance anticholinergic drugs) because the effects of loperamide could be enhanced.
Administration of itraconazole with loperamide (4 mg single dose) increased loperamide plasma levels 3- to 4-fold. In addition, gemfibrozil, a CYP2C8 inhibitor, increased the AUC of loperamide 2-fold. Concomitant use of itraconazole and gemfibrozil with loperamide raised the mean Cmax and AUC of loperamide about 2- and 13-fold, respectively. This increase did not lead to measurable CNS effects.
The concomitant administration of loperamide (16mg 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.
The clinical relevance of these pharmacokinetic interactions, when loperamide is given at recommended dosages (2 mg, up to 12 mg maximum daily dose), is unknown.

4.6 Fertility, pregnancy and lactation
A limited amount of data from the use of loperamide in pregnant women is available. In one of two epidemiological studies the use of loperamide during early pregnancy suggested a possible moderate increased risk for hypospadias, however, an increased risk for major malformations could not be identified. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. Safety in human pregnancy has not been established, although from animal studies there are no indications that loperamide HCl possesses any teratogenic or embryotoxic properties.
If possible, the use of loperamide should be avoided during the first trimester of pregnancy, however, it may be used during the second and third trimester of pregnancy

Breast-feeding
Small amounts of loperamide may appear in human breast milk. Therefore, this medicine is not recommended during breast-feeding. Women who are pregnant or breast-feeding infants should therefore be advised to consult their doctor for appropriate treatment.
Fertility
Only high doses of loperamide hydrochloride affected female fertility in non-clinical studies

4.7 Effects on ability to drive and use machines
Loperamide hydrochloride has moderate influence on the 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 hydrochloride.
Therefore, it is advisable to use caution when driving or operating machinery

4.8 Undesirable effects
Common adverse effects like Headache, Dizziness, Constipation, Nausea, and Flatulence. **Uncommon adverse effects** like Somnolence, Abdominal pain, abdominal discomfort, Dry mouth, abdominal pain upper, Vomiting, Dyspepsia.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to National Regulatory Agents.

4.9 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), urinary retention and ileus may occur. Children may be more sensitive to CNS effects than adults.
In individuals who have ingested overdoses of loperamide HCl, cardiac events such as QT interval prolongation, torsades de pointes, other serious ventricular arrhythmias, cardiac arrest and syncope have been observed. Fatal cases have also been reported. Overdose can unmask existing Brugada syndrome.
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, the patient should be monitored closely for at least 48 hours to detect possible CNS depression.

5. Pharmacological properties
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Antipropulsives

ATC Code: A07DA03.

Mechanism of action

Loperamide binds to the opiate receptor in the gut wall, reducing propulsive peristalsis, increasing intestinal transit time and enhancing resorption of water and electrolytes. Loperamide increases the tone of the anal sphincter, which helps reduce fecal incontinence and urgency.

Clinical efficacy and safety

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

5.2 Pharmacokinetic properties

Absorption: Most ingested loperamide is absorbed from the gut, but because of significant first pass metabolism, systemic bioavailability is only approximately 0.3%.

Distribution: Studies on distribution in rats show a high affinity for the gut wall with a preference for binding to receptors of the longitudinal muscle layer. The plasma protein binding of loperamide is 95%, mainly to albumin. Non-clinical data have shown that loperamide is a Pglycoprotein substrate.

Biotransformation: Loperamide is almost completely extracted by the liver, where it is predominantly metabolized, conjugated and excreted via the bile. Oxidative N-demethylation is the main metabolic pathway for loperamide and is mediated mainly through CYP3A4 and CYP2C8. Due to this very high first pass effect, plasma concentrations of unchanged drug remain extremely low.

Elimination: The half-life of loperamide in man is about 11 hours with a range of 9-14 hours. Excretion of the unchanged loperamide and the metabolites mainly occurs through the feces. **Paediatric Population:** No pharmacokinetic studies were performed in the paediatric population. It is expected that pharmacokinetic behavior of loperamide and drug-drug interactions with loperamide will be like those in adults.

5.3 Preclinical safety data

Not Applicable

6. Pharmaceutical particulars

6.1 List of excipients

Sr. No.	Excipients
1.	Sodium Starch Glycolate
2.	Microcrystalline Cellulose
3.	Dried Lactose
4.	Colloidal silicon dioxide
5.	Magnesium Stearate
6.	EHG Capsule: Size “2”

	Cap- Green Body- Grey

6.2 Incompatibilities
Not Applicable

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Store below 30°C. Protect from light and moisture.

6.5 Nature and contents of container
10 x 10 Capsules packed in Alu PVC blister packed in printed carton with insert.

6.6 Special precautions for disposal and other handling
No special requirements

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURER
Marketing Authorization Holder:
ZAIN PHARMA LTD.
Plot No: 209/13741, Colchester Park,
Go-Down No.1, 2, 3, Off Mombasa Road,
Behind Nice and Lovely House,
P.O. Box: 100167-00101, Nairobi, Kenya

8. Marketing Authorization Number:
H2020/22425

9. Date of First Registration
14/06/2026

10. Date of Revision of the Text:
14/06/2026