Safety Data Sheet

Loperamide Hydrochloride Capsules, USP
Strength: 2 mg
Pack Size: HDPE Bottle pack 100's
HDPE Bottle pack 500's

Revision No.: 02

EMERGENCY OVERVIEW

Each Loperamide Hydrochloride Capsules, USP intended for oral administration contains Loperamide Hydrochloride and excipients generally considered to be non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

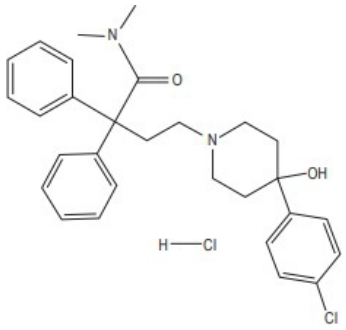
Section 1. Identification

Identification of the product

Product Name: Loperamide Hydrochloride Capsules, USP

Formula: Loperamide hydrochloride USP, 4-(p-chlorophenyl)-4-hydroxy-N,N-dimethyl-a,a-diphenyl-1-piperidinebutyramide monohydrochloride

Chemical Name:



Manufacturer / supplier identification

Company: **Zydus Lifesciences Ltd., Matoda, India**

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Recommended use / Therapeutic Category	Loperamide hydrochloride capsules are indicated for the control and symptomatic relief of acute nonspecific diarrhea in patients 2 years of age and older and of chronic diarrhea in adults associated with inflammatory bowel disease. Loperamide hydrochloride capsules are also indicated for reducing the volume of discharge from ileostomies.
Restriction on Use / Contraindications:	• Avoid Loperamide hydrochloride dosages higher than recommended in adult or pediatric patients 2 years of age and older due to the risk of serious cardiac adverse reactions. • Loperamide hydrochloride is contraindicated in: o Pediatric patients less than 2 years of age due to the risks of respiratory depression and serious cardiac adverse reactions (see WARNINGS). o Patients with a known hypersensitivity to loperamide hydrochloride or to any of the excipients. o Patients with abdominal pain in the absence of diarrhea. o Patients with acute dysentery, which is characterized by blood in stools and high fever. • o Patients with acute ulcerative colitis. o Patients with bacterial enterocolitis caused by invasive organisms including Salmonella, Shigella and Campylobacter. o Patients with pseudomembranous colitis (e.g., Clostridium difficle) associated with the use of broad-spectrum antibiotics.

Section 2. Hazard(s) Identification

Adverse Effects	• The adverse effects reported during clinical investigations of Loperamide hydrochloride are difficult to distinguish from symptoms associated with the diarrheal syndrome. Adverse experiences recorded during clinical studies with Loperamide hydrochloride were generally of a minor and self-limiting nature. They were more commonly observed during the treatment of chronic diarrhea.

Over dosage	• The use of higher than recommended loperamide hydrochloride doses may result in life-threatening cardiac, CNS and respiratory adverse reactions.
Pregnancy Comments	Teratology studies have been performed in rats using oral loperamide hydrochloride doses of 2.5 mg/kg/day, 10 mg/kg/day and 40 mg/kg/day and in rabbits using oral doses of 5 mg/ kg/day, 20 mg/kg/day and 40 mg/kg/day. These studies have revealed no evidence of impaired fertility or harm to the fetus at doses up to 10 mg/kg/day in rats (5 times the human dose based on body surface area comparison) and 40 mg/kg/day in rabbits (43 times the human dose based on body surface area comparison). Treatment of rats with oral doses of 40 mg/kg/ day (21 times the human dose based on a body surface area comparison) produced marked impairment of fertility. The studies produced no evidence of teratogenic activity. There are no adequate and well controlled studies in pregnant women. Loperamide hydrochloride should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Pregnancy Category	Category C

Section 3. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component:		
Loperamide Hydrochloride	310 mcg/day	34552-83-5
Inactive ingredients:		
Lactose Monohydrate	Not Found	10039-26-6
Providone K	Not Found	9003-39-8
Sodium starch Glycolate	Not Found	9063-38-1
Microcrystalline Cellulose	Not Found	9004-34-6
Colloidal Silicon Dioxide	Not Found	**7631-86-9**
Magnesium stearate	Not Found	557-04-0

Section 4. First -aid measures

In Case of Inhalation	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

In Case of Skin Contact	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
In Case of Eye Contact	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
In Case of Swallowed	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice

Section 5. Fire -fighting measures

Fire Fighting Instructions	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.
Flammable Properties:	May be combustible at high temperature.
Hazardous Combustion Products:	Under fire conditions, hazardous fumes will be present.
Suitable & Unsuitable Extinguishing media:	Small fire: dry chemical, CO_2 or water spray. Large fire: dry chemical, CO_2, alcohol resistant foam or water spray. Do not get water inside containers

Section 6. Accidental Release Measures

Method and material for containment	On land, sweep or shovel into suitable containers. Minimize generation of dust.
Clean-up Procedures	Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains

Section 7. Handling and Storage

Precaution and safe handling	Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabelled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.
Condition for safe Storage	Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabelled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.
Storage Condition	Store in original container, tightly sealed, protected from direct sunlight and moisture. Preserve in well-closed containers. Protected from light.

Section 8. Exposure Control / Personal Protection

Personal Proactive Equipment

Eyes	Wear appropriate protective eyeglasses or chemical safety goggles. Wear appropriate gloves to prevent skin exposure.
Skin / Clothing	Wear appropriate protective clothing to minimize contact with skin.
Respirators	Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirators

Thermal Hazards	For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

Section 9. Physical and chemical properties

Physical States

Solubility	Freely soluble in methanol and in chloroform; slightly soluble in water and in dilute acids; very slightly soluble in isopropyl alcohol	**Decomposition Temperature:**	225 °C, 437 °F
Boiling point	90 °C, 734 °F	**Melting Point**	220 - 228)°C, (428-442.4)°F
Evaporation rate	No Data	**Vapour density**	No Data
Reactivity in water	No Data	**Vapour pressure**	No Data
% Volatile by volume	No Data	**Specific gravity**	No Data

Section 10. Stability and Reactivity

Chemical Stability	Stable under recommended storage conditions
Condition to avoid	Moisture, sunlight and extreme temperatures
Incompatibles	Strong oxidizing agents. Bases. Reducing agents. Acids.
Hazard Decomposition	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur.

Section 11. Toxicological information

Acute Toxicity	Oral: Rat: LD50: (mg/kg): 185 Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available
Skin Corrosion/Irritation	Due to lack of data the classification is not possible
Serious eye damage / Eye Irritation	Due to lack of data the classification is not possible
Respiratory Sensitization	Due to lack of data the classification is not possible

Skin Sensitization	Based on available data, the classification criteria are not met. Suspected skin sensitiser: The Toolbox profiler Protein binding alerts for skin sensitization by OASIS v1.3 gives an alert for skin sensitisation.

Section 12. Ecological information

Persistence and Degradability	Suspected persistent in the environment: The Danish QSAR database contains information indicating that the substance is predicted as non-readily biodegradable.
Bio-accumulative Potential	Log Pow: 5.13 (20°C), has potential for bioaccumulation.
Mobility in Soil	Slightly soluble in water
Toxicity	EC50: 48 Hr: Crustacea: (mg/L): Not available LC50: 96 Hr: Fish: (mg/L): Not available EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available

Section 13. Disposal Consideration

Dispose in accordance with local, state, and federal regulations

Section 14. Transport Information

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG). In accordance with ADR / RID / IMDG / IATA / AND.

Section 15. Regulatory Information

ANDA No :217471

Section 16. Other information

None

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The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.