SAFETY DATA SHEET

Hydromorphone Hydrochloride ER Tablets

1. IDENTIFICATION

Manufacturer:

Ascent Pharmaceuticals Inc
400 S. Technology Drive
Central Islip, NY 11722
USP

Emergency Phone:

1-855-221-1622

Common Name: Hydromorphone Hydrochloride ER Tablets Extended Release Tablets
Synonym(s): Not Applicable

Trade Name(s): Hydromorphone Hydrochloride ER Tablets Extended Release Tablets, 8 mg, 12 mg, 16 mg and 32 mg.

2.HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Caution Statement Narcotic. Accidental Ingestion of large amounts may be harmful. Read package insert prior to use. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. Suspected of damaging fertility or the unborn child. May cause drowsiness or dizziness

Potential Health Effects

Routes of Entry: Ingestion

Eyes: May cause irritation.

Skin Contact: with skin may cause irritation. Allergic reactions are possible, Rash.

Inhalation: Narcotic. Can irritate the respiratory passages and cause sneezing, coughing, hypersensitivity. Other symptoms will parallel ingestion.

Ingestion: If swallowed: Immediately call a poison center/doctor. Never give anything by mouth to a victim who is unconscious or is having convulsions. Do not induce vomiting without advice from poison control center. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Rinse

mouth. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs

Most important symptoms/effects, acute and delayed: Narcosis. Exposure may cause sedation, pinpoint pupils, mood alterations, nausea, vomiting, constipation, respiratory depression; also tolerance, dependence and withdrawal. Decrease in motor functions. Respiratory disorder. May cause allergic respiratory and skin reactions. Dusts may irritate the respiratory tract, skin and eyes.

3.COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	**CAS**	**Concentration***
		8 mg, 12 mg, 16 mg and 32 mg
Hydromorphone Hydrochloride	71-68-1	≈ 4.7 % to 9.4 %
Excipients	NA	≈ 90.6-95.3 %

* All Concentrations are percent by weight.

4. FIRST AID MEASURES

Inhalation: If breathing is difficult, move to fresh air, if not breathing give artificial respiration. Get medical attention immediately.

Skin Contact: Wash with soap and water for at least 15 minutes. Get medical attention if symptoms occur.

Eye Contact: Any material that contacts the eye should be washed out immediately with water for at least 15 minutes. If easy to do, remove contact lenses if worn. Get medical attention if symptoms persist.

Ingestion: Call a physician or poison control center immediately. Never give anything by mouth to a victim who is unconscious or is having convulsions. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.

5.FIRE-FIGHTING MEASURES

Extinguishing Media: Use water spray, dry chemical, carbon dioxide or material appropriate for fire in surrounding area

Unusual Fire & Explosion Hazards: Not Applicable.

Special Fire Fighting Procedures: Wear full protective clothing and self-contained breathing apparatus.

Protective Measures: Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

6.ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment. Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all firefighting procedures.

Environmental precautions: Do not release in to the environment.

Spill Cleanup methods: Sweep up or vacuum up spillage and collect in suitable container for disposal. Should not be released into the environment. Do not flush to sewer. All clean-up operations should be witnessed by more than one individual. The amount of material collected should be assessed and documented. See section 13 of the SDS.

7.HANDLING AND STORAGE

Handling: Special handling and storage requirements must be observed to assure compliance with Drug Enforcement Administration regulations. All employees who handle this material should be thoroughly trained to handle it safely. Empty containers may contain residual material; therefore, empty containers should be handled with care and disposed of properly. Do not breathe dust. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.

Storage: This material must be stored in a locked cabinet in a Controlled Substance Storage Room, per the requirements of regulations of the DEA and FDA at Controlled Room Temperature: 20º to 25º C (68º to 77º F). Store the medicine in a tight, light resistant container at room temperature, away from heat, moisture, and direct light.

8.EXPOSURE CONTROLS / PERSONAL PROTECTION

Compressed tablets are not considered hazardous under normal handling procedures and protective equipment is not required. The following are recommended for manufacturing or other situations where exposure to the powder may occur.

Protective Measures: Not required when handling tablets or containers. Ventilation should be matched to conditions.

Respiratory Protection: Not required when handling tablets or containers. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to conditions.

Hand Protection: Chemical resistant gloves.

Eye Protection: Wear safety glasses with side shields (or goggles). If the work environment or activity involves dusty conditions, mist or aerosols, wear the appropriate goggles. Wear a face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and Body Protection: Not required when handling tablets. If containers are compromised or exposure is likely --wear: Goggles, Lab Coat and Gloves

Hygiene Measures: Wash skin thoroughly with soap and water.

9.PHYSICAL AND CHEMICAL PROPERTIES

Physical Properties:
Physical State: Solid
Form: Tablets
Appearance:
Hydromorphone Hydrochloride ER Tablets Extended Release Tablets, 8 mg: Light pink to pink film coated, round, biconvex tablets printed with "266" in black ink on one side of the tablet.
Hydromorphone Hydrochloride ER Tablets Extended Release Tablets, 12 mg: Light yellow to yellow film coated, round, biconvex tablets printed with "267" in black ink on one side of the tablet.
Hydromorphone Hydrochloride ER Tablets Extended Release Tablets, 16 mg: Light beige to beige film coated, round, biconvex tablets printed with "268" in black ink on one side of the tablet.

Hydromorphone Hydrochloride ER Tablets Extended Release Tablets, 32 mg: White to off white film coated, round, biconvex tablets printed with "269" in black ink on one side of the tablet.

10. STABILITY AND REACTIVITY

Possibility of hazardous reactions: Stable under ordinary conditions of use and storage.

Conditions to avoid: Excessive heat & Moisture.

Incompatible materials: Alkalis.

Hazardous Decomposition products: May produce Carbon oxides, Nitrogen oxides (NOx) & Hydrogen chloride.

11.TOXICOLOGICAL INFORMATION

Acute Toxicity:
Active Ingredient:
LD50 Oral (mouse): 104 mg/kg intravenous
84 mg/kg subcutaneous

Carcinogenicity: Not listed as a carcinogen or potential carcinogen by NTP, IARC Monographs or OSHA.

12.ECOLOGICAL INFORMATION

General information: The information presented below pertains to the individual ingredients, and not to the mixture(s) or final formulations.

Ecotoxicity: No data available.

Acute toxicity (Aquatic invertebrates): No data available.

Bioaccumulation: No data available.

Mobility: No data available.

13.DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of waste must be in accordance with all applicable Federal, State and local laws. Notify site Drug Enforcement Agency compliance officer and local DEA office for appropriate disposal procedures. Processing, use or contamination of this

product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations.

14.TRANSPORT INFORMATION

DOT: Not Regulated

IMDG: Not regulated

ICAO/IATA: Not Regulated

15.REGULATORY INFORMATION

Stated regulatory information chosen primarily for possible usage of Ascent Pharmaceutical, Inc. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulatory Information

CERLA Hazardous Substance List (40 CFR 302.4): None

TSCA : None

Section 302 Extremely Hazardous Substance: None

SARA 311/312 Hazardous chemical: yes

Drug Enforcement Administration (DEA) (21 CFR 1308.11-15): Schedule II – 9150

Hazard categories

Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

16.OTHER INFORMATION

NFPA ratings Health: 3 Flammability: 0 Reactivity: 0
SDS Sections Revised: New

GLOSSARY:

SDS	Safety Data Sheet
NA	Not Applicable
CAS Number	Chemical Abstract Service Registry Number
NTP	National Toxicology Program
NIOSH	National Institute for Occupational Safety and Health
DOT	Department of Transportation
IMDG	International Maritime Dangerous Goods Code
ICAO	International Civil Aviation Organization
IATA	International Air Transport Association
IMO	International Maritime Organization
TSCA	Toxic Substances Control Act
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
SARA	Superfund Amendments and Reauthorization Act
OSHA	Occupational Safety and Health Administration
DEA	Drug Enforcement Administration

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