

52778



Material Safety Data Sheet: Ketorolac Tromethamine Injection, USP

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Section I: Identification

Trade/Common Names Ketorolac Tromethamine Injection, USP
Chemical Names (±)-5-benzoyl- 2,3-dihydro-1H-pyrrrolizine-1-carboxylic acid, compound with 2-amino-2-(hydroxymethyl)-1,3-propanediol (active ingredient)
Use Nonsteroidal anti-inflammatory drug. Member of the pyrrolo-pyrrole group. Formulated for intravenous (IV) or intramuscular (IM) injection. Refer to package insert for additional information.
DOT Designation Ethanol Solutions, 3, UN1170, PGII
IATA Designation Ethanol Solutions, 3, UN1170, PGII

Section II: Ingredients

This is a prescription drug product intended for IV or IM injection only. For medical information, refer to the Package Insert.

Component (CAS Number)	ACGIH TLV	OSHA PEL	OTHER LIMITS	NOTES
Ketorolac tromethamine (74103-07-04), 1.5%	a*	b*	NE	NONE
Alcohol, USP (64-17-5), 10%	1000 ppm TWA	1000 ppm, 1900 mg/m ³	1000 ppm TWA (NIOSH)	NONE
Sodium Chloride (7647-14-5), <1	a*	b*	NE	NONE
Water (7732-18-5), >80%	NE	NE	NE	NONE

KEY
 NE = Not Established
 * Particulates not otherwise classified (PNOC), TWA
 Inhalable particulate: 10 mg/m³, Respirable particulate: 3 mg/m³
 * Particulates not otherwise regulated (PNOR), TWA
 Total dust: 15 mg/m³, Respirable fraction: 5 mg/m³
KEY TO NOTES: - NONE - none of the regulations below applies to this component
 (1) (Suspect) carcinogen-OSHA, ACGIH, NTP or IARC
 (2) SARA Title III Section 313 chemical
 (3) SARA Title III Extremely Hazardous Substance
 (4) CERCLA Hazardous Substance and Reportable Quantities
 (5) RCRA Hazardous Waste
 *Final product is a solution. The hazards of the components are not anticipated. Particulate exposure hazard may be produced by aerosolization.

EMERGENCY OVERVIEW

This solution (15-30 mg/ml) is shipped in a syringe containing either 1 or 2 milliliter (0.4 or 0.7 fl oz) of solution. Needle packaged with syringe.
CAUTION: Solution contains an ingredient that is flammable. Solution not Evaluated for Occupational Exposure.
 Solution contact may be irritating to the eyes and skin. Ingestion may cause stomach and intestinal bleeding, ulceration and perforation (hole).
 May cause acute renal failure, liver failure, and severe allergic reaction. Pregnant women or fetus may be at risk.

Section III: Physical Data

Boiling Point	Estimated at 100°C (212°F) (Water)	% Volatile (by weight)	Not available
Vapor Pressure (mm Hg)	Not determined	Evaporation Rate (n-butyl acetate = 1)	< 1
Vapor Density (air = 1)	Not determined	pH	6.9-7.9
Specific Gravity (water = 1)	Approximately 1 @ 20°C	Solubility in Water	Complete
Appearance and Odor	Clear, slight yellow aqueous sterile solution		

Section IV: Fire and Explosion Hazard Data

Flash Point	Estimated to be 120°F (49°C)	Method	Not Available
LEL/UEL	<3.3 -19% by volume in air (based on ethanol)		
Extinguishing Media	Water, foam, or all purpose dry chemical		
Special Fire Fighting Procedures	Product contains ethanol		
Unusual Fire/Explosion Hazards	May emit toxic fumes (see Hazardous Decomposition Products)		

Section V: Reactivity Data

Stable	Yes
Incompatibility (materials to avoid)	Strong oxidizers
Hazardous Decomposition Products	Carbon dioxide, carbon monoxide. Hazardous polymerization will not occur.

Material Safety Data Sheet: Ketorolac Tromethamine Injection, USP**Section VI: Health Hazard Data****Effects of Overexposure****Eyes****Skin****Inhalation****Ingestion****Accidental Injection****Other Adverse Effects****Medical Conditions Aggravated by Exposure****Toxicity Data****Acute**

ketorolac tromethamine

Alcohol, USP

Chronic**SOLUTION NOT EVALUATED FOR OCCUPATIONAL EXPOSURE**

May cause redness, irritation, or discomfort.

May cause redness, irritation, or discomfort.

Unlikely under normal conditions of handling or usage (requires creation of an aerosol).

Unlikely under normal conditions of handling or usage. May cause stomach upset (nausea, vomiting), drowsiness, headache, and stomach and intestinal bleeding, ulceration, and perforation (hole).

Overdose can cause abdominal pain, peptic ulcers, and metabolic acidosis. Refer to package insert for complete listing of warnings and adverse reactions.

May cause acute renal failure, anaphylactic and anaphylactoid (severe allergic) reactions and liver failure.

Peptic ulcers disease, stomach and intestinal bleeding, kidney damage, high risk of bleeding, child birth, nursing mothers, and allergies to aspirin, other non-steroidal anti-inflammatory drugs, or any component of the product.

The following acute toxicology information is for pure ketorolac tromethamine or Alcohol, USP

LDLo Intramuscular, Women 15 mg/kg/6D intermittent LD₅₀ Oral, Rat 200-225 mg/kgLD₅₀ Oral, Mouse 3450 mg/kg LD₅₀ Inhalation, Rat 20000 ppm/10H

Irritation, Skin (Draize), Rabbit, 20mg/24 H: Moderate Irritation, Eye (Draize), Rabbit, 500mg: Severe

No evidence of tumorigenicity was observed after oral administration of ketorolac tromethamine to mice for 18 months or rats for 2 years. No evidence of mutagenicity was seen in the AMES test, unscheduled DNA synthesis and repair, and in forward mutation assays. Increased incidence of chromosomal aberrations in Chinese hamster ovarian cell was seen at concentration of 1590 mg/ml and higher. The carcinogenic and mutagenic potential of Ketorolac Tromethamine Injection, USP have not been evaluated. Pregnancy Class C. Reproductive studies performed during organogenesis in rabbits and rats have been negative with oral ketorolac tromethamine doses of 3.6 mg/kg (0.37 times the human AUC) and 10 mg/kg (1 times the human AUC), respectively. In rats, oral doses at 1.5 mg/kg (0.14 times the human AUC) produced dystocia (abnormal labor or child birth) and higher pup death. Impairment of fertility did not occur in male or female rats after oral doses of 9 mg/kg and 16 mg/kg of ketorolac tromethamine, respectively. There are no adequate and well-controlled studies of ketorolac tromethamine in pregnant women.

Emergency First Aid Procedures**Eyes****Skin****Inhalation****Ingestion****Accidental Injection**

Flush with large amounts of water for at least 15 minutes. If redness or irritation occurs, seek medical attention.

Wash the affected area with mild detergent and water. Rinse affected area with water for at least 15 minutes. If redness or irritation occurs, seek medical attention.

Remove person to fresh air. Administer artificial respiration or CPR as needed. Seek medical attention.

If swallowed, call a physician or poison control center for most current information. Refer to package insert.

Treat symptomatically for reaction to drug. Refer to package insert.

Section VII: Spill or Leak Procedures**Steps to be taken if material is released or spilled**

For small releases of the material, absorb spilled liquid with rags or similar materials. Large or uncontrolled releases should be responded to by trained personnel using pre-planned procedures. Proper protective equipment should be used.

Waste Disposal Method

Dispose of solution in accordance with country, regional, federal, state, and local regulations. Dispose of used syringe and needle in accordance with medical waste regulation and guidelines.

Section VIII: Personal Protection**Respiratory Protection**

Perform exposure monitoring for this product and its components to ensure that employees are not exposed to levels greater than applicable regulatory limits. If exposure levels exceed regulatory limits, implement a respiratory protection program including respiratory protection that is in compliance with OSHA 29 CFR 1910.134 (in the US) or equivalent regulation in other regions. Fire fighting requires the use of a self-contained breathing apparatus with full face piece and positive pressure mode.

Ventilation

General ventilation is adequate.

Skin

Latex, nitrile, rubber, or other impervious gloves recommended. Lab coat or equivalent.

Eyes

Safety glasses. Face shield recommended where splashing or aerosolization may occur.

Section IX: Special Precautions**Handling and Storage**

Store between 15-30°C (59-86°F). Protect from light. Caution, each disposable syringe is supplied with a needle.

To the best of our knowledge, the information contained herein is accurate. However, neither Baxter Healthcare Corporation nor any of its divisions or subsidiaries assumes any legal responsibility for use or reliance upon this information. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

Prepared By:

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Replaces Information Dated: Not Applicable**Date Issued:** January 2000