

Safety data sheet

Etomidate Injection USP

Strength: 2mg/mL

Pack Size: 10X10 mL & 10X20mL Glass

Revision No.: 01

EMERGENCY OVERVIEW

Etomidate Injection intended for Intravenous injection contains Etomidate and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

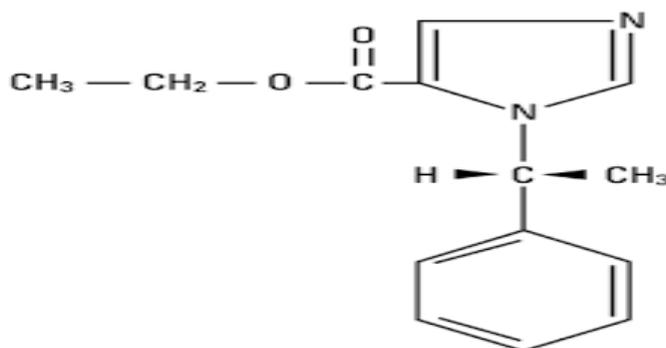
Section 1. Identification

Identification of the product

Product name: Etomidate Injection

Formula: $C_{14}H_{16}N_2O_2$

Chemical Name: (R) – (+) –ethyl-1-(1-phenylethyl)-1H-imidazole-5-carboxylate



Company:

Cadila Healthcare Ltd. Ahmedabad, India

Address:

Sarkhej – Bavla. N.H. 8A, Moraiya. Tal. Sanand.
Dist. Ahmedabad – 382210. State: Gujarat. India

Contact for information:

Tel.: +91 79 6868100 Fax: +91 79 3750319

Emergency Telephone No.

Tel.: +91 79 6868100

Recommended use /
Therapeutic Category:

Etomidate is intended for use as a general anesthetic

Restriction on Use /
Contraindications

Etomidate is contraindicated in patients who have shown hypersensitivity to it.

Warning

Intravenous Etomidate should be administered only by persons trained in the administration of general anesthetics and in the management of complications encountered during the conduct of general anesthesia.

Safety data sheet

Etomidate Injection USP

Strength: 2mg/mL

Pack Size: 10X10 mL & 10X20mL Glass

Revision No.: 01

Because of the hazard of prolonged suppression of endogenous Cortisol and aldosterone production, this formulation is not intended for administration by prolonged infusion.

Precaution

Do not administer unless solution is clear and container is undamaged. Discard unused portion.

Section 2. Hazard(s) Information

Dose and Administration

Etomidate injection, USP is intended for administration only by the intravenous route. The dose for induction of anesthesia in adult patients and in pediatric patients above the age of ten (10) years will vary between 0.2 and 0.6 mg/kg of body weight, and it must be individualized in each case. The usual dose for induction in these patients is 0.3 mg/kg, injected over a period of 30 to 60 seconds. There are inadequate data to make dosage recommendations for induction of anesthesia in patients below the age of ten (10) years; therefore, such use is not recommended.

Geriatric patients may require reduced doses of etomidate. Smaller increments of intravenous etomidate may be administered to adult patients during short operative procedures to supplement subpotent anesthetic agents, such as nitrous oxide. The dosage employed under these circumstances, although usually smaller than the original induction dose, must be individualized. There are insufficient data to support this use of etomidate for longer adult procedures or for any procedures in pediatric patients; therefore, such use is not recommended. The use of intravenous fentanyl and other neuroactive drugs employed during the conduct of anesthesia may alter the etomidate dosage requirements. Consult the prescribing information for all other such drugs before using.

Premedication

Etomidate injection, USP is compatible with commonly administered pre-anesthetic medications, which may be employed as indicated and dosage recommendations for maintenance of anesthesia.

Etomidate hypnosis does not significantly alter the usual dosage requirements of neuromuscular blocking agents employed for endotracheal intubation or other purposes shortly after induction of anesthesia. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

To prevent needle-stick injuries, needles should not be recapped, purposely bent, or broken by hand.

Safety data sheet

Etomidate Injection USP

Strength: 2mg/mL

Pack Size: 10X10 mL & 10X20mL Glass

Revision No.: 01

Adverse Effect

The most frequent adverse reactions associated with use of intravenous etomidate are transient venous pain on injection and transient skeletal muscle movements, including myoclonus:

1. Transient venous pain was observed immediately following intravenous injection of etomidate in about 20% of the patients, with considerable difference in the reported incidence (1.2% to 42%). This pain is usually described as mild to moderate in severity but it is occasionally judged disturbing. The observation of venous pain is not associated with a more than usual incidence of thrombosis or thrombophlebitis at the injection site. Pain also appears to be less frequently noted when larger, more proximal arm veins are employed and it appears to be more frequently noted when smaller, more distal, hand or wrist veins are employed.

2. Transient skeletal muscle movements were noted following use of intravenous etomidate in about 32% of the patients, with considerable difference in the reported incidence (22.7% to 63%). Most of these observations were judged mild to moderate in severity but some were judged disturbing. The incidence of disturbing movements was less when 0.1 mg of fentanyl was given immediately before induction. These movements have been classified as myoclonic in the majority of cases (74%), but averting movements (7%), tonic movements (10%), and eye movements (9%) have also been reported. No exact classification is available, but these movements may also be placed into three groups by location:

- a. Most movements are bilateral. The arms, legs, shoulders, neck, chest wall, trunk and all four extremities have been described in some cases, with one or more of these muscle groups predominating in each individual case. Results of electroencephalographic studies suggest that these muscle movements are a manifestation of disinhibition of cortical activity; cortical electroencephalograms, taken during periods when these muscle movements were observed, have failed to reveal seizure activity.

- b. Other movements are described as either unilateral or having a predominance of activity of one side over the other. These movements sometimes resemble a localized response to some stimuli, such as venous pain on injection, in the lightly anesthetized patient (averting movements). Any muscle group or groups may be involved, but a predominance of movement of the arm in which the intravenous infusion is started is frequently noted.

- c. Still other movements probably represent a mixture of the first two types.

Skeletal muscle movements appear to be more frequent in patients who also manifest venous pain on injection.

Safety data sheet

Etomidate Injection USP

Strength: 2mg/mL

Pack Size: 10X10 mL & 10X20mL Glass

Revision No.: 01

Other Adverse Observations

Respiratory System

Hyperventilation, hypoventilation, apnea of short duration (5 to 90 seconds with spontaneous recovery); laryngospasm, hiccup and snoring suggestive of partial upper airway obstruction have been observed in some patients. These conditions were managed by conventional countermeasures.

Circulatory System

Hypertension, hypotension, tachycardia, bradycardia and other arrhythmias have occasionally been observed during induction and maintenance of anesthesia. One case of severe hypotension and tachycardia, judged to be anaphylactoid in character, has been reported.

Gastrointestinal System

Postoperative nausea and/or vomiting following induction of anesthesia with etomidate is probably no more frequent than the general incidence. When etomidate was used for both induction and maintenance of anesthesia in short procedures such as dilation and curettage, or when insufficient analgesia was provided, the incidence of postoperative nausea and/or vomiting was higher than that noted in control patients who received thiopental.

Over Dose Effect

Overdosage may occur from too rapid or repeated injections. Too rapid injection may be followed by a fall in blood pressure. No adverse cardiovascular or respiratory effects attributable to etomidate overdose have been reported.

In the event of suspected or apparent overdosage, the drug should be discontinued, a patent airway established (intubate, if necessary) or maintained and oxygen administered with assisted ventilation, if necessary.

The LD₅₀ of etomidate administered intravenously to rats is 20.4 mg/kg.

Medical Condition

Individuals on monoamine oxidase inhibitors (MAO) or individuals currently using depressant drug or substances.

Contraindication

Etomidate is contraindicated in patients who have shown hypersensitivity to it.

Warning

Intravenous Etomidate should be administered only by persons trained in the administration of general anesthetics and in the management of complications encountered during the conduct of general anesthesia.

Because of the hazard of prolonged suppression of endogenous Cortisol and aldosterone production, this formulation is not intended for administration by prolonged infusion.

Safety data sheet

Etomidate Injection USP

Strength: 2mg/mL

Pack Size: 10X10 mL & 10X20mL Glass

Revision No.: 01

Precaution

Do not administer unless solution is clear and container is undamaged. Discard unused portion.

Pregnancy Comments

Etomidate has been shown to have an embryocidal effect in rats when given in doses 1 and 4 times the human dose. There are no adequate and well-controlled studies in pregnant women. Etomidate should be used during pregnancy only if the potential benefit justifies the potential risks to the fetus. Etomidate has not been shown to be teratogenic in animals. Reproduction studies with etomidate have been shown to:

- a. Decrease pup survival at 0.3 and 5 mg/kg in rats (approximately 1X and 16X human dosage) and at 1.5 and 4.5 mg/kg in rabbits (approximately 5X and 15X human dosage). No clear dose-related pattern was observed.
- b. Increase slightly the number of stillborn fetuses in rats at 0.3 and 1.25 mg/kg (approximately 1X and 4X human dosage).
- c. Cause maternal toxicity with deaths of 6/20 rats at 5 mg/kg (approximately 16X human dosage) and 6/20 rabbits at 4.5 mg/kg (approximately 15X human dosage).

Pregnancy Category

C

Section 3. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component: Etomidate	Not Found	33125-97-2
Inactive Ingredients: Propylene Glycol 35%	Not Found	57-55-6

Section 4. First aid measures

General

Inhalation

Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Contact with Eye

Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Safety data sheet

Etomidate Injection USP

Strength: 2mg/mL

Pack Size: 10X10 mL & 10X20mL Glass

Revision No.: 01

Incompatibilities:

Store according to label and/or product insert information. Store away from oxidizers, acids, and bases.

Section 8. Exposure controls / personal protection

Respiratory protection

Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N99 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin protection

If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

Eye protection

Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls

Engineering controls are normally not needed during the normal use of this product.

Section 9 Physical and chemical properties

Appearance/Physical State

Liquid

Color

Sterile, nonpyrogenic solution

Odor

NA

Odor Threshold:

NA

pH:

6.0 (4.0 to 7.0)

Melting point/Freezing point:

No Data Available

Initial Boiling Point/Boiling Point Range:

No Data Available

Safety data sheet

Etomidate Injection USP

Strength: 2mg/mL

Pack Size: 10X10 mL & 10X20mL Glass

Revision No.: 01

Evaporation Rate: No Data Available

Flammability (solid, gas): No Data Available

Upper/Lower Flammability or Explosive Limits: No Data Available

Vapor Pressure: No Data Available

Vapor Density: No Data Available

Specific Gravity: No Data Available

Solubility: No Data Available

Other information No Data Available

Section 10. Stability and Reactivity

Conditions to avoid No data available **Stable** Stable

Decomposition products Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx) and nitrogen oxides (NOx).

Hazardous Reaction No data available

Incompatibilities Not determined

Section 11. Toxicological information

General Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specific formulation.

Target organ Based on clinical use, possible target organ include the central nervous system, respiratory system, cardiovascular system and adrenal gland.

Other Not Applicable

Safety data sheet

Etomidate Injection USP

Strength: 2mg/mL

Pack Size: 10X10 mL & 10X20mL Glass

Revision No.: 01

Section 12. Ecological information

Do not allow product to enter drinking water supplies, waste water or soil

Section 13. Disposal Consideration

Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 14. Transport Information

The product is not hazardous when shipping via air (IATA), ground(DOT) or sea(IMDG).

Section 15. Regulatory Information

Generic Medicine. Approved by USFDA & the ANDA Number is 202360

Section 16. Other Information

None

Date of issue: 28/05/2015

Supersedes edition of: 00

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