

Safety Data Sheet

Ranitidine Injection, USP

Strength: 25 mg/mL **Pack Size:** 2-mL single-dose vials (10 vials per carton) and 6-mL multi-dose vials (Single) **Revision No.:** 02

EMERGENCY OVERVIEW

Ranitidine Injection is a sterile product contains ranitidine (as the hydrochloride) as an active ingredient and other excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

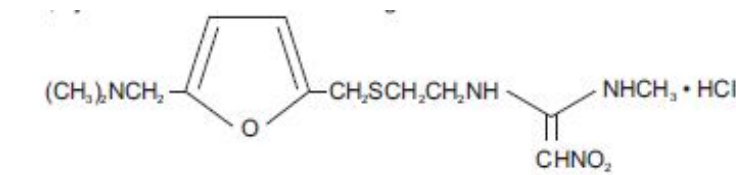
Section 1. Identification

Identification of the product

Product name: Ranitidine Injection, USP

Formula $C_{13}H_{22}N_4O_3S \cdot HCl$

Chemical Name: N[2-[[[5[(dimethylamino)methyl]-2-furanyl]methyl]thio]ethyl]-N'-methyl-2-nitro-1,1-ethenediamine, hydrochloride



Ranitidine hydrochloride

Recommended use / Therapeutic Category Histamine H₂-receptor antagonist

Restriction on Use / Contraindications: Ranitidine injection is contraindicated for patients known to have hypersensitivity to the drug.

Section 2. Hazard(s) Information

Dose and Administration In patients who are unable to take oral medication, ranitidine hydrochloride may be administered parenterally according to the following recommendations:
Intramuscular Injection: 50 mg (2 mL) every 6 to 8 hours. (No dilution necessary.)
Intermittent Intravenous Injection:

- Intermittent Bolus: 50 mg (2 mL) every 6 to 8 hours. Dilute ranitidine injection, 50 mg, in 0.9% sodium chloride injection or other compatible IV solution to a concentration no greater than 2.5 mg/mL (20 mL). Inject at a rate no greater than 4 mL/min (5 minutes).
- Intermittent Infusion: 50 mg (2 mL) every 6 to 8 hours. Dilute

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ranitidine injection, 50 mg, in 5% dextrose injection or other compatible IV solution to a concentration no greater than 0.5 mg/mL (100 mL). Infuse at a rate no greater than 5 to 7 mL/min (15 to 20 minutes).

Continuous Intravenous Infusion:

Add ranitidine injection to 5% dextrose injection or other compatible IV solution. Deliver at a rate of 6.25 mg/hour (e.g., 150 mg [6 mL] of ranitidine injection in 250 mL of 5% dextrose injection at 10.7 mL/hour).

Pediatric Use:

the recommended dose in pediatric patients is for a total daily dose of 2 to 4 mg/kg, to be divided and administered every 6 to 8 hours, up to a maximum of 50 mg given every 6 to 8 hours.

Adverse Effects

Central Nervous System: Rarely, malaise, dizziness, somnolence, insomnia, and vertigo. Rare cases of reversible mental confusion, agitation, depression, and hallucinations have been reported, predominantly in severely ill elderly patients. Rare cases of reversible blurred vision suggestive of a change in accommodation have been reported. Rare reports of reversible involuntary motor disturbances have been received.

Cardiovascular: As with other H₂-blockers, rare reports of arrhythmias such as tachycardia, bradycardia, asystole, atrioventricular block, and premature ventricular beats.

Gastrointestinal: Constipation, diarrhea, nausea/vomiting, abdominal discomfort/pain, and rare reports of pancreatitis.

Hepatic: In normal volunteers, SGPT values were increased to at least twice the pretreatment levels in 6 of 12 subjects receiving 100 mg intravenously 4 times daily for 7 days, and in 4 of 24 subjects receiving 50 mg intravenously 4 times daily for 5 days. There have been occasional reports of hepatocellular, cholestatic, or mixed hepatitis, with or without jaundice. In such circumstances, ranitidine should be immediately discontinued. These events are usually reversible, but in rare circumstances death has occurred. Rare cases of hepatic failure have also been reported.

Musculoskeletal: Rare reports of arthralgias and myalgias.

Hematologic: Blood count changes (leukopenia, granulocytopenia, and thrombocytopenia) have occurred in a few patients. These were usually reversible. Rare cases of agranulocytosis, pancytopenia, sometimes with marrow hypoplasia, and aplastic anemia and exceedingly rare cases of acquired immune hemolytic anemia have been reported.

Endocrine: Controlled studies in animals and humans have shown no stimulation of any pituitary hormone by ranitidine hydrochloride and no antiandrogenic activity, and cimetidine-induced gynecomastia and impotence

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in hypersecretory patients have resolved when ranitidine hydrochloride has been substituted. However, occasional cases of impotence and loss of libido have been reported in male patients receiving ranitidine hydrochloride, but the incidence did not differ from that in the general population. Rare cases of breast symptoms and conditions, including galactorrhea and gynecomastia, have been reported in both males and females.

Integumentary: Rash, including rare cases of erythema multiforme. Rare cases of alopecia and vasculitis.

Respiratory: A large epidemiological study suggested an increased risk of developing pneumonia in current users of histamine-2-receptor antagonists (H₂RAs) compared to patients who had stopped H₂RA treatment, with an observed adjusted relative risk of 1.63 (95% CI, 1.07 to 2.48). However, a causal relationship between use of H₂RAs and pneumonia has not been established.

Other: Rare cases of hypersensitivity reactions (e.g., bronchospasm, fever, rash, eosinophilia), anaphylaxis, angioneurotic edema, acute interstitial nephritis, and small increases in serum creatinine.

Over Dose Effect There has been virtually no experience with overdosage with ranitidine injection. In addition, abnormalities of gait and hypotension have been reported.

Contraindications Ranitidine injection is contraindicated for patients known to have hypersensitivity to the drug.

Pregnancy Comments No adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed.

Pregnancy Category B

Section 3. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component:		
Ranitidine hydrochloride	Not Found	66357-59-3
Inactive Ingredients :		
Phenol	Not Found	108-95-2
Monobasic potassium phosphate	Not Found	7778-77-0
Dibasic sodium phosphate	Not Found	7558-79-4

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Section 4. First -aid measures

General

Inhalation

Remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.

Contact with skin

Immediately wash skin with soap and copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.

Contact with eyes

Immediately flush eyes with copious amounts of water for at least 15 minutes. Seek medical advice

Ingestion

If swallowed, wash out mouth with water, provided person is conscious. Seek medical advice. Remove and wash/dispose of contaminated clothing promptly.

Overdose Treatment

When overdosage occurs, clinical monitoring and supportive therapy should be employed.

Section 5. Fire - fighting measures

Flash point

Not Found

Upper Flammable Limit:

Not Found

Auto-Ignition Temperature:

Not Found

Lower Flammable Limit:

Not Found

Extinguishing Media

Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.

Fire and Explosion Hazard

This material is assumed to be combustible at high temperature.

Fire Fighting Procedure

As with all fires, evacuate personnel to a safe area. Fire fighter should use self-contained breathing equipment and protective clothing.

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Section 6. Accidental Release Measures

Spill Response Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

Section 7. Handling and Storage

Storage Store at 20° to 25°C (68° to 77°F). Do not freeze. Protect from light.

Incompatibilities No data available.

Section 8. Exposure controls / personal protection

Respiratory Protection Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.

Skin Protection Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.

Eye protection Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.

Protective Clothing Protective clothing is not normally necessary, however it is good practice to use apron.

Engineering Controls: Enclosed local exhaust ventilation is required at points of dust, fume or vapor generation. HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapors.

Section 9. Physical and chemical properties

Appearance Ranitidine injection, USP is a clear, colorless to yellow, nonpyrogenic liquid.

Solubility Soluble in water. **Odour** Odorless.
Sparingly soluble in alcohol.

Boiling point No Data Available **Melting Point** About 140° C

Evaporation rate No Data Available **Vapour density** No Data Available

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Reactivity in water	No Data Available	Evaporation rate	No Data Available
Percentage Volatile by volume	No Data Available	Specific gravity	No Data Available
Vapour pressure	No Data Available	Other information	Not Applicable

Section 10. Stability and Reactivity

Condition to avoid	Avoid exposure to extreme heat, light and moisture.	Stable	Stable under predefined storage and handling conditions. Avoid excessive heat. Protect from freezing.
Decomposition Products	No Data Available	Hazardous Reaction	No data available.
Incompatibilities	No data available.		

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	Eye contact, Skin contact and inhalation is not great risk.		
Other	Intravenous LD ₅₀ values in mice and rats were 77 and 83 mg/kg, respectively.		

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 91534.

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Section 16. Other information

None

Date of issue: 28/05/2015

Supersedes edition of: 01

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.