

RIMSO-50®

Brand of dimethyl sulfoxide irrigation, USP STERILE AND NON-PYROGENIC

Description: RIMSO-50® brand of dimethyl sulfoxide (DMSO) 50% w/w Aqueous Solution for intravesical instillation. Each mL contains 0.54 gm dimethyl sulfoxide. Intravesical instillation for the treatment of interstitial cystitis. NOT FOR I.M. OR I.V. INJECTION. RX ONLY.

The active component of RIMSO-50® solution is dimethyl sulfoxide which has the empirical formula C₂H₆OS. Dimethyl sulfoxide is a clear, colorless and essentially odorless liquid which is miscible with water and most organic solvents. Other physical characteristics include: molecular weight 78.13, melting point 18.3° C, and a specific gravity of 1.096.

Clinical Pharmacology: Dimethyl sulfoxide is metabolized in man by oxidation to dimethyl sulfone or by reduction to dimethyl sulfide. Dimethyl sulfoxide and dimethyl sulfone are excreted in the urine and feces. Dimethyl sulfoxide is eliminated through the breath and skin and is responsible for characteristic odor from patients on dimethyl sulfoxide medication. Dimethyl sulfone can persist in serum for longer than two weeks after a single intravesical instillation. No residual accumulation of dimethyl sulfoxide has occurred in man or lower animals who have received treatment for protracted periods of time. Following topical application, dimethyl sulfoxide is absorbed and generally distributed in the tissues and body fluids.

Indications and Usage: RIMSO-50® brand of dimethyl sulfoxide is indicated for the symptomatic relief of patients with interstitial cystitis. RIMSO-50® solution has not been approved as being safe and effective for any other indication. There is no clinical evidence of effectiveness of dimethyl sulfoxide in the treatment of bacterial infections of the urinary tract.

Contraindications: None known

Warnings: Dimethyl sulfoxide can initiate the liberation of histamine and there has been occasional hypersensitivity reaction with topical administration of dimethyl sulfoxide. This hypersensitivity has been reported in one patient receiving intravesical RIMSO-50® solution. The physician should be cognizant of this possibility in prescribing RIMSO-50® solution. If anaphylactoid symptoms develop, appropriate therapy should be instituted.

Precautions: Changes in the refractive index and lens opacities have been seen in monkeys, dogs, and rabbits given high doses of dimethyl sulfoxide chronically. Since lens changes were noted in animals, full eye evaluations, including slit lamp examinations, are recommended prior to and periodically during treatment.

Approximately every six months patients receiving dimethyl sulfoxide should have a biochemical screening, particularly liver and renal function tests, and complete blood count.

Intravesical instillation of RIMSO-50® solution may be harmful to patients with urinary tract malignancy because of dimethyl sulfoxide-induced vasodilation.

Some data indicate that dimethyl sulfoxide potentiates other concomitantly administered medications.

Pregnancy Category C. Dimethyl sulfoxide caused teratogenic responses in hamsters, rats and mice when administered interperitoneally at high doses (2.5 to 12 g/kg). Oral or topical doses of dimethyl sulfoxide did not cause problems of reproduction in rats, mice and hamsters. Topical doses (5 g/kg first two days, then 2.5 g/kg last eight days) produced terata in rabbits, but in another study, topical doses of 1.1 g/kg days 3 through 16 of gestation failed to produce any abnormalities. There are no adequate and well controlled studies in pregnant women. Dimethyl sulfoxide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when dimethyl sulfoxide is administered to a nursing woman.

Safety and effectiveness in children have not been established.

Adverse Reactions: A garlic-like taste may be noted by the patient within a few minutes after instillation of RIMSO-50® brand of dimethyl sulfoxide. This taste may last several hours and because of the presence of metabolites, an odor on the breath and skin may remain for 72 hours.

Transient chemical cystitis has been noted following instillation of dimethyl sulfoxide.

The patient may experience moderately severe discomfort on administration. Usually this becomes less prominent with repeated administration.

Drug Abuse and Dependence: None known.

Overdosage: The oral LD₅₀ of dimethyl sulfoxide in the dog is greater than 10 gm/kg. It is improbable that this dosage level could be obtained with intravesical instillation of RIMSO-50® solution in the patient.

In case of accidental oral ingestion, specific measures should be taken to induce emesis. Additional measures which may be considered are gastric lavage, activated charcoal and force diuresis.

Dosage and Administration: Instillation of 50 mL of RIMSO-50® brand of dimethyl sulfoxide directly into the bladder may be accomplished by catheter or syringe and allow to remain for 15 minutes. Application of an analgesic lubricant gel such as lidocaine jelly to the urethra is suggested prior to insertion of the catheter to avoid spasm. The medication is expelled by spontaneous voiding.

It is recommended that the treatment be repeated every two weeks until maximum symptomatic relief is obtained. Thereafter, time intervals between therapy may be increased appropriately.

Administration of oral analgesic medication suppositories containing belladonna and opium prior to the instillation of RIMSO-50® solution can reduce bladder spasm.

In patients with severe interstitial cystitis with very sensitive bladders, the initial treatment, and possibly the second and third (depending on patient response) should be done under anesthesia. (Saddle block has been suggested.)

How Supplied: Bottles contain 50 mL of sterile and non-pyrogenic RIMSO-50® (50% w/w dimethyl sulfoxide aqueous solution).

Dimethyl sulfoxide is clear and colorless.

Protect from strong light. Store at room temperatures 59° to 86° F (15° to 30°C).

NDC #67457-177-50

Manufactured for: Bioniche Pharma USA LLC, Lake Forest, IL 60045
Manufactured by: Bioniche Teo., Inverin, Co. Galway, Ireland

References:

1. Photographs courtesy of Interstitial Cystitis Association and C. Lowell Parsons, M.D.
2. Erickson DR. Interstitial Cystitis: Update on Etiologies and Therapeutic Options. J Women's Health & Gender-Based Med 1999; 6:745.
3. Parkin J, et al. Intravesical Dimethyl Sulfoxide (DMSO) for Interstitial Cystitis - A Practical Approach. Urology, 1997; 49(SA, Suppl):106.
4. Sant GR, et al. Intravesical 50% Dimethyl Sulfoxide (RIMSO-50® solution) in Treatment of Interstitial Cystitis. Urology 1987; 29(4, Suppl):19.

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