

PDR®
47
EDITION
1993

BLACKWELL SANDERS MATHENY
WEARY & LOMBARDI

PHYSICIANS'
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1993 Supplements for revisions

FORMULATIONS AND COMPOSITION

vitamins and 72 trace minerals in adult/child
E + Zinc with lysine and bioflavonoids
 compounded B-complex vitamins in a herbal
 E 12 1000% of USRDA per dose
 high concentration 25,000 I.U. per spray
 meets the nutrient needs during syndrome
 herbal combination with Ascorbic Acid and D-Al-
 bery supplement nutrient needs, aid smoking

dietary snack replacements with a combination
 Acids, B-6, B-12 and Chromium Polynicotinate

AND ADMINISTRATION

1 dose (except Vit. A formula, 1 spray = 1 dose).
 into mouth 2 sprays 4 times per day.

APPLIED

Intra-Oral sprays are supplied in a 13.3 ml vial
 approximately 240 metered sprays from a non-

EDUCATIONAL MATERIAL

additional literature on oral absorption will be
 upon request to Regency Medical Research.

Research Industries Corporation

Pharmaceutical Division
 3054 SOUTH 300 WEST
 MOVALE, UTAH 84047

50

of dimethyl sulfoxide)

FACT OVERVIEW

component of Rimso®-50 is sterile and pyrogen-
 dimethyl sulfoxide.

USES

50 has been proved to be clinically effective for the
 relief of patients with interstitial cystitis.

SAFETY INFORMATION

instillation of Rimso®-50 may be harmful to
 with urinary tract malignancy because of dimethyl
 induced vasodilation.

dimethyl sulfoxide can initiate the liberation of histamine
 there have been occasional hypersensitivity reactions
 topical administration.

dimethyl sulfoxide should be used during pregnancy only if
 potential benefit justifies the potential risk to the fetus.

PRESCRIBING INFORMATION

50

of dimethyl sulfoxide)

DESCRIPTION

50, brand of dimethyl sulfoxide (DMSO)
 Aqueous Solution for intravesical instillation.
 contains 0.54 gm dimethyl sulfoxide STERILE AND
 FREE.

instillation for the treatment of interstitial

FOR I.M. OR I.V. INJECTION

NOTION

law prohibits dispensing without a prescription.

component of RIMSO®-50 is dimethyl sulfoxide
 has the empirical formula C₂H₆S:

dimethyl sulfoxide is a clear, colorless and essentially odor-
 liquid which is miscible with water and most organic
 solvents. Other physical characteristics include: molecular
 78.13, melting point 18.4°C, and a specific gravity of

CLINICAL PHARMACOLOGY

dimethyl sulfoxide is metabolized in man by oxidation to
 dimethyl sulfone or by reduction to dimethyl sulfide. Di-
 methyl sulfoxide and dimethyl sulfone are excreted in the
 urine and feces. Dimethyl sulfide is eliminated through the
 skin and is responsible for the characteristic odor
 associated with dimethyl sulfoxide medication. Dimethyl
 sulfoxide can persist in serum for longer than two weeks after
 intravesical instillation. No residual accumulation

Following topical application, dimethyl sulfoxide is absorbed
 and generally distributed in the tissues and body fluids.

INDICATIONS AND USAGE

RIMSO®-50 (dimethyl sulfoxide) is indicated for the symp-
 tomatic relief of patients with interstitial cystitis. RIMSO®-
 50 has not been approved as being safe and effective for any
 other indication. There is no clinical evidence of effective-
 ness of dimethyl sulfoxide in the treatment of bacterial infec-
 tions of the urinary tract.

CONTRAINDICATIONS

None known.

WARNINGS

Dimethyl sulfoxide can initiate the liberation of histamine
 and there has been an occasional hypersensitivity reaction
 with topical administration of dimethyl sulfoxide. This hyper-
 sensitivity has been reported in one patient receiving
 intravesical RIMSO®-50. The physician should be cognizant
 of this possibility in prescribing RIMSO®-50. If anaphy-
 lactic 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 di-
 methyl sulfoxide chronically. Since lens changes were noted
 in animals, full eye evaluations, including slit lamp exami-
 nations are recommended prior to and periodically during
 treatment.

Approximately every six months patients receiving di-
 methyl sulfoxide should have a biochemical screening, par-
 ticularly liver and renal function tests, and complete blood
 count. Intravesical instillation of RIMSO®-50 may be harm-
 ful to patients with urinary tract malignancy because of di-
 methyl sulfoxide-induced vasodilation.

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

Pregnancy Category C. Dimethyl sulfoxide caused terato-
 genic responses in hamsters, rats and mice when adminis-
 tered intraperitoneally at high doses (2.5-12 gm/kg). Oral or
 topical doses of dimethyl sulfoxide did not cause problems of
 reproduction in rats, mice and hamsters. Topical doses (5
 gm/kg first two days, then 2.5 gm/kg-last eight days) pro-
 duced terata in rabbits, but in another study, topical doses of
 1.1 gm/kg days 3 through 16 of gestation failed to produce
 any abnormalities. There are no adequate and well con-
 trolled 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 exer-
 cised when dimethyl sulfoxide is administered to a nursing
 woman.

Safety and effectiveness in children has been
 established.
 Information available to be given to the patient is reprinted
 at the end of this text.

ADVERSE REACTIONS

A garlic-like taste may be noted by the patient within a few
 minutes after instillation of RIMSO®-50 (dimethyl sulfox-
 ide). 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 instilla-
 tion 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 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
 forced diuresis.

DOSAGE AND ADMINISTRATION

Instillation of 50 ml of RIMSO®-50 (dimethyl sulfoxide)
 directly into the bladder may be accomplished by catheter or
 aseptic syringe and allowed to remain for 15 minutes. Appli-
 cation 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 ob-
 tained. Thereafter, time intervals between therapy may be
 increased appropriately.
 Administration of oral analgesic medication or suppositories

In patients with severe interstitial cystitis with very sensi-
 tive 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 pyrogen-free
 RIMSO®-50 (50% w/w dimethyl sulfoxide aqueous
 solution).

Dimethyl sulfoxide is clear and colorless

Protect from strong light

Store at room temperature (59° to 86°F) (15° to 30°C)

Do not autoclave

NDC #0433-0433-05

For additional information concerning RIMSO®-50, contact
 the Pharmaceutical Division, Research Industries Corpora-
 tion, Salt Lake City, Utah

RIMSO®-50 is manufactured by Tera Pharmaceuticals,
 Inc., Buena Park, California, for the Pharmaceutical Divi-
 sion, Research Industries Corp., Salt Lake City, Utah.

Rexar Pharmacial Corp.
 396 ROCKAWAY AVENUE
 VALLEY STREAM, NY 11581

OBETROL™ Tablets

DESCRIPTION

A single entity amphetamine product combining the neutral
 sulfate salts of dextroamphetamine and amphetamine, with
 the dextro isomer of amphetamine saccharate and d,l am-
 phetamine aspartate.

EACH TABLET CONTAINS:	10 mg.	20 mg.
Dextroamphetamine Saccharate	2.5 mg.	5 mg.
Amphetamine Aspartate	2.5 mg.	5 mg.
Dextroamphetamine Sulfate	2.5 mg.	5 mg.
Amphetamine Sulfate	2.5 mg.	5 mg.
Inactive Ingredients: Sucrose, Lactose, Cornstarch, Acacia and Magnesium Stearate.		

Colors: Obetrol 10 contains FD&C Blue #1
 Colors: Obetrol 20 contains FD&C Yellow #6 as a color
 additive

HOW SUPPLIED

Obetrol 10 mg Blue scored tablet IMPRINTED OP-32

- NDC 0477-5432-01 for 100's
- NDC 0477-5432-05 for 500's
- NDC 0477-5432-10 for 1000's

Obetrol 20 mg Orange scored tablet IMPRINTED OP-33

- NDC 0477-5433-01 for 100's
- NDC 0477-5433-05 for 500's
- NDC 0477-5433-10 for 1000's

Dispense in a tight container as defined in the USP.
 Store at controlled room Temperature 15-30°C (59°-86°F).

Shown in Product Identification Section, page 424

DEXTROAMPHETAMINE SULFATE, USP
 5 mg and 10 mg Tablets

Shown in Product Identification Section, page 424

OBY-TRIM Capsules

Phentermine Hydrochloride, USP, 30 mg
 (equivalent to 24 mg phentermine base)

REXATAL Tablets

Phenobarbital, USP, (1/4 gr) 16.2 mg
 Hyoscyamine Sulfate, USP, 0.1037 mg
 Atropine Sulfate, USP, 0.0194 mg
 Scopolamine Hydrobromide, USP, 0.0065 mg

X-TROZINE Tablets

X-TROZINE Capsules
 Phendimetrazine Tartrate, USP, 35 mg

TRANS-DERMAL PATCH
 GEL-CAPSULE