EXELDERM- sulconazole nitrate solution
Journey Medical Corporation

Exelderm®

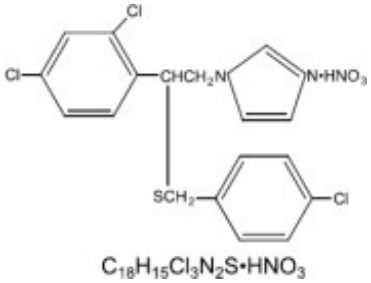
(sulconazole nitrate, USP)
Solution, 1.0%

Rx only

For topical use only. Not for ophthalmic use.

DESCRIPTION

EXELDERM (sulconazole nitrate, USP) SOLUTION, 1.0% is a broad-spectrum antifungal agent intended for topical application. Sulconazole nitrate, USP, the active ingredient in EXELDERM SOLUTION, is an imidazole derivative with antifungal and antiyeast activity. Its chemical name is (±)-1-[2,4-dichloro-β-[(p-chlorobenzyl)-thio]-phenethyl] imidazole mononitrate and it has the following chemical structure:



Sulconazole nitrate, USP is a white to off-white crystalline powder with a molecular weight of 460.77. It is freely soluble in pyridine; slightly soluble in ethanol, acetone, and chloroform; and very slightly soluble in water. It has a melting point of about 130°C.

EXELDERM SOLUTION contains sulconazole nitrate, USP 10 mg/mL in a solution of propylene glycol, poloxamer 407, polysorbate 20, butylated hydroxyanisole, and purified water, with sodium hydroxide and, if necessary, nitric acid added to adjust the pH.

CLINICAL PHARMACOLOGY

Sulconazole nitrate is an imidazole derivative that inhibits the growth of the common pathogenic dermatophytes including *Trichophyton rubrum, Trichophyton mentagrophytes, Epidermophyton floccosum,* and *Microsporum canis.* It also inhibits the organism responsible for tinea versicolor, *Malassezia furfur,* and certain gram-positive bacteria.

A maximization test with sulconazole nitrate solution showed no evidence of irritation or contact sensitization.

INDICATIONS AND USAGE

EXELDERM (sulconazole nitrate, USP) SOLUTION, 1.0% is a broad-spectrum antifungal

agent indicated for the treatment of tinea cruris and tinea corporis caused by *Trichophyton rubrum, Trichophyton mentagrophytes, Epidermophyton floccosum,* and *Microsporum canis;* and for the treatment of tinea versicolor. Effectiveness has not been proven in tinea pedis (athlete's foot).

Symptomatic relief usually occurs within a few days after starting EXELDERM SOLUTION and clinical improvement usually occurs within one week.

CONTRAINDICATIONS

EXELDERM (sulconazole nitrate, USP) SOLUTION, 1.0% is contraindicated in patients who have a history of hypersensitivity to any of the ingredients.

PRECAUTIONS

General

EXELDERM (sulconazole nitrate, USP) SOLUTION, 1.0% is for external use only. Avoid contact with the eyes. If irritation develops, the solution should be discontinued and appropriate therapy instituted.

Information for Patients

Patients should be told to use EXELDERM SOLUTION as directed by the physician, to use it externally only, and to avoid contact with the eyes.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies to determine carcinogenic potential have not been performed. *In vitro* studies have shown no mutagenic activity.

Pregnancy

Sulconazole nitrate has been shown to be embryotoxic in rats when given in doses 125 times the human dose (in mg/kg). The drug at this dose given orally to rats also resulted in prolonged gestation and dystocia. Several females died during the perinatal period, most likely due to labor complications. Sulconazole nitrate was not teratogenic in rats or rabbits at oral doses of 50 mg/kg/day.

There are no adequate and well-controlled studies in pregnant women. Sulconazole nitrate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

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 sulconazole nitrate is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in children have not been established.

Geriatric Use

Clinical studies of EXELDERM SOLUTION, 1.0%, did not include sufficient numbers of patients aged 65 years and over to determine whether they respond differently than younger patients. Other reported clinical experience has not identified differences in responses between elderly and younger patients.

ADVERSE REACTIONS

There were no systemic effects and only infrequent cutaneous adverse reactions in 370 patients treated with sulconazole nitrate solution in controlled clinical trials. Approximately 1% of these patients reported itching and 1% burning or stinging. These complaints did not usually interfere with treatment.

DOSAGE AND ADMINISTRATION

A small amount of solution should be gently massaged into the affected and surrounding skin areas once or twice daily.

Symptomatic relief usually occurs within a few days after starting EXELDERM (sulconazole nitrate) SOLUTION, 1.0%, and clinical improvement usually occurs within 1 week. To reduce the possibility of recurrence, tinea cruris, tinea corporis, and tinea versicolor should be treated for 3 weeks.

If significant clinical improvement is not seen after 4 weeks of treatment, an alternate diagnosis should be considered.

HOW SUPPLIED

EXELDERM (sulconazole nitrate, USP) SOLUTION, 1.0% is a clear, slightly viscous, colorless to slightly yellow liquid with a slight characteristic odor. It is supplied as follows:

30 mL plastic bottle – NDC 69489-721-30

Avoid excessive heat, above 40° C (104° F), and protect from light.

To report SUSPECTED ADVERSE REACTIONS, contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

JOURNEY®
MEDICAL CORPORATION

Manufactured for:
Journey Medical Corp.
Scottsdale, AZ 85258
www.JMCderm.com

141112 Revised March 2021

Principal Display Panel – 30 mL Bottle Label

NDC 69489-721-30

Exelderm®

(sulconazole
nitrate, USP)
Solution, 1.0%

30 mL

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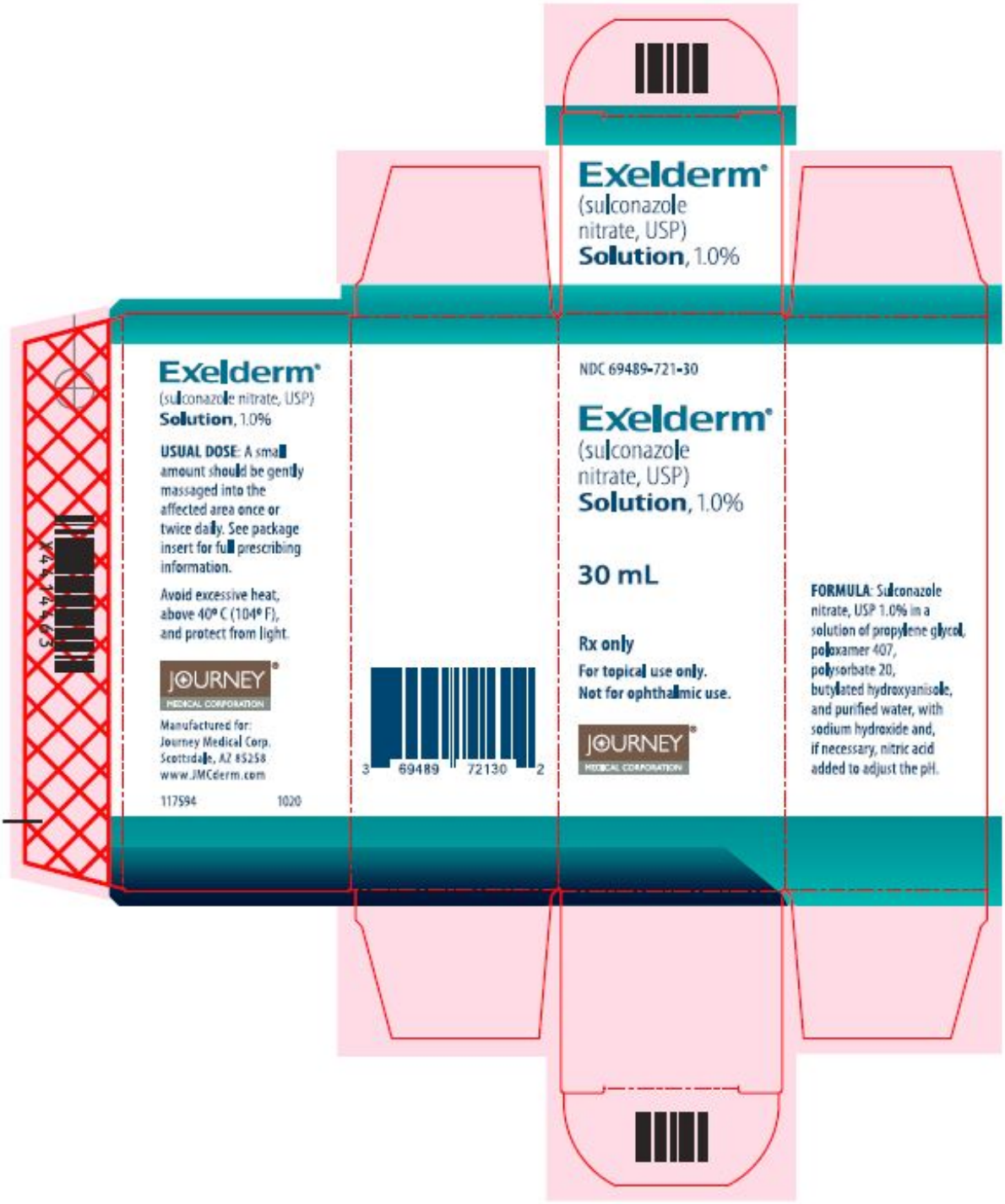

Principal Display Panel – 30 mL Bottle Label

Exelderm® NDC 69489-721-30

(sulconazole nitrate, USP)
Solution, 1.0%

Rx only

For topical use only.

Not for ophthalmic use.

30 mL

EXELDERM

sulconazole nitrate solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69489-721
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Sulconazole Nitrate (UNII: 1T89100D5U) (SULCONAZOLE - UNII:5D9HAA5Q5S)	Sulconazole Nitrate	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Propylene glycol (UNII: 6DC9Q167V3)	
Poloxamer 407 (UNII: TUF2IVW3M2)	
Polysorbate 20 (UNII: 7T1F30V5YH)	
Butylated Hydroxyanisole (UNII: REK4960K2U)	
Water (UNII: 059QF0KO0R)	
Sodium hydroxide (UNII: 55X04QC32I)	
Nitric acid (UNII: 411VRN1TV4)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69489-721-30	1 in 1 CARTON	06/07/2019	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69489-721-05	5 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/15/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018738	06/07/2019	

Labeler - Journey Medical Corporation (079640860)

Establishment

Name	Address	ID/FEI	Business Operations
DPT Laboratories, Ltd.		832224526	ANALYSIS(69489-721) , MANUFACTURE(69489-721) , LABEL(69489-721) , PACK(69489-721)

Revised: 11/2022 Journey Medical Corporation