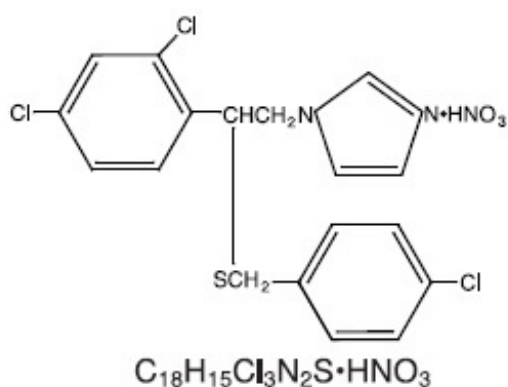


EXELDERM- sulconazole nitrate cream
Sun Pharmaceutical Industries, Inc.

Exelderm® (sulconazole nitrate, USP)
Cream, 1.0%
For topical use only. Not for ophthalmic use.

DESCRIPTION

EXELDERM (sulconazole nitrate, USP) CREAM, 1.0% is a broad-spectrum antifungal agent intended for topical application. Sulconazole nitrate, USP the active ingredient in EXELDERM CREAM, is an imidazole derivative with *in vitro* antifungal and antiyeast activity. Its chemical name is (±)-1-[2,4-Dichloro-β-[(pchlorobenzyl)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 CREAM contains sulconazole nitrate, USP 10 mg/g in an emollient cream base consisting of propylene glycol, stearyl alcohol, isopropyl myristate, cetyl alcohol, polysorbate 60, sorbitan monostearate, glyceryl stearate (and) PEG-100 stearate, ascorbyl palmitate, and purified water, with sodium hydroxide and/or nitric acid added to adjust the pH.

CLINICAL PHARMACOLOGY

Sulconazole nitrate is an imidazole derivative with broad-spectrum antifungal activity that inhibits the growth *in vitro* of the common pathogenic dermatophytes including *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Epidermophyton floccosum* and *Microsporum canis*. It also inhibits (*in vitro*) the organism responsible for tinea versicolor, *Malassezia furfur*. Sulconazole nitrate has been shown to be active *in vitro* against the following microorganisms, although clinical efficacy has not been established: *Candida albicans* and certain gram positive bacteria.

A modified Draize test showed no allergic contact dermatitis and a phototoxicity study showed no phototoxic or photoallergic reaction to sulconazole nitrate cream. Maximization tests with sulconazole nitrate cream showed no evidence of contact sensitization or irritation.

INDICATIONS AND USAGE

EXELDERM (sulconazole nitrate, USP) CREAM, 1.0% is an antifungal agent indicated for the treatment

of tinea pedis (athlete's foot), tinea cruris, and tinea corporis caused by *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Epidermophyton floccosum*, and *Microsporum canis*,* and for the treatment of tinea versicolor.

CONTRAINDICATIONS

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

PRECAUTIONS

General

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

Information for Patients

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

Carcinogenesis, Mutagenesis and Impairment of Fertility

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

Pregnancy

There are no adequate and well controlled studies in pregnant women. Sulconazole nitrate should be used during pregnancy only if clearly needed. Sulconazole nitrate has been shown to be embryotoxic in rats when given in doses of 125 times the adult human dose (in mg/kg). The drug was not teratogenic in rats or rabbits at oral doses of 50 mg/kg/day.

Sulconazole nitrate given orally to rats at a dose 125 times the human dose resulted in prolonged gestation and dystocia. Several females died during the prenatal period, most likely due to labor complications.

Nursing Mothers

It is not known whether sulconazole nitrate is 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.

* Efficacy for this organism in the organ system was studied in fewer than ten infections.

Geriatric Use

Clinical studies of EXELDERM CREAM, 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 1185 patients treated with sulconazole nitrate cream in controlled clinical trials. Approximately 3% of these patients reported

itching, 3% burning or stinging, and 1% redness. These complaints did not usually interfere with treatment.

CLINICAL STUDIES

In a vehicle-controlled study for the treatment of tinea pedis (moccasin type) due to *T. rubrum*, after 4-6 weeks of treatment 69% of patients on the active drug and 19% of patients on the drug vehicle had become KOH and culture negative. In addition, 68% of patients on the active drug and 20% of patients on the drug vehicle showed a good or excellent clinical response.

DOSAGE AND ADMINISTRATION

A small amount of cream should be gently massaged into the affected and surrounding skin areas once or twice daily, except in tinea pedis, where administration should be twice daily.

Early relief of symptoms is experienced by the majority of patients and clinical improvement may be seen fairly soon after treatment is begun; however, tinea corporis/cruris and tinea versicolor should be treated for 3 weeks and tinea pedis for 4 weeks to reduce the possibility of recurrence.

If significant clinical improvement is not seen after 4 to 6 weeks of treatment, an alternate diagnosis should be considered.

HOW SUPPLIED

EXELDERM (sulconazole nitrate, USP) CREAM, 1.0% is a smooth glossy white to off-white cream having slight characteristic odor. It is supplied as follows:

15 g tube - NDC 10631-101-15

30 g tube - NDC 10631-101-30

60 g tube - NDC 10631-101-60

Avoid excessive heat, above 40°C (104°F).

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

Manufactured by:

DPT Laboratories Inc.

San Antonio, TX 78215

Distributed by:

Sun Pharmaceutical Industries, Inc.

Cranbury, NJ 08512

Revised May 2018

Exelderm Cream 15 g Carton



Exelderm Cream 30g Carton



Exelderm Cream 30g Tube

Rx only

NDC 10631-101-30

Exelderm[®]
(sulconazole nitrate, USP)
Cream, 1.0%

Avoid excessive heat, above 40° C (104° F).

For topical use only.

Not for ophthalmic use.

USUAL DOSE: See package insert.

FORMULA: Sulconazole nitrate, USP

1.0% in an emollient cream base

of propylene glycol, stearyl

alcohol, isopropyl myristate, cetyl

alcohol, polysorbate 60, sorbitan

monostearate, glyceryl stearate

(and) PEG-100 stearate, ascorbyl

palmitate, and purified water, with

sodium hydroxide and, if necessary,

nitric acid to adjust pH.



NET WT. 30 g

See crimp for lot number
and expiration date

RANBAXY

Jacksonville, FL 32257 USA

106227

1212

Exelderm Cream 60g Tube

Rx only

NDC 10631-101-60

Exelderm[®]
(sulconazole nitrate, USP)
Cream, 1.0%

Avoid excessive heat, above 40° C (104° F).

For topical use only.

Not for ophthalmic use.

USUAL DOSE: See package insert.

FORMULA: Sulconazole nitrate, USP 1.0% in an emollient cream base of propylene glycol, stearyl alcohol, isopropyl myristate, cetyl alcohol, polysorbate 60, sorbitan monostearate, glyceryl stearate (and) PEG-100 stearate, ascorbyl palmitate, and purified water, with sodium hydroxide and, if necessary, nitric acid to adjust pH.

NET WT. 60 g



See crimp for lot number and expiration date

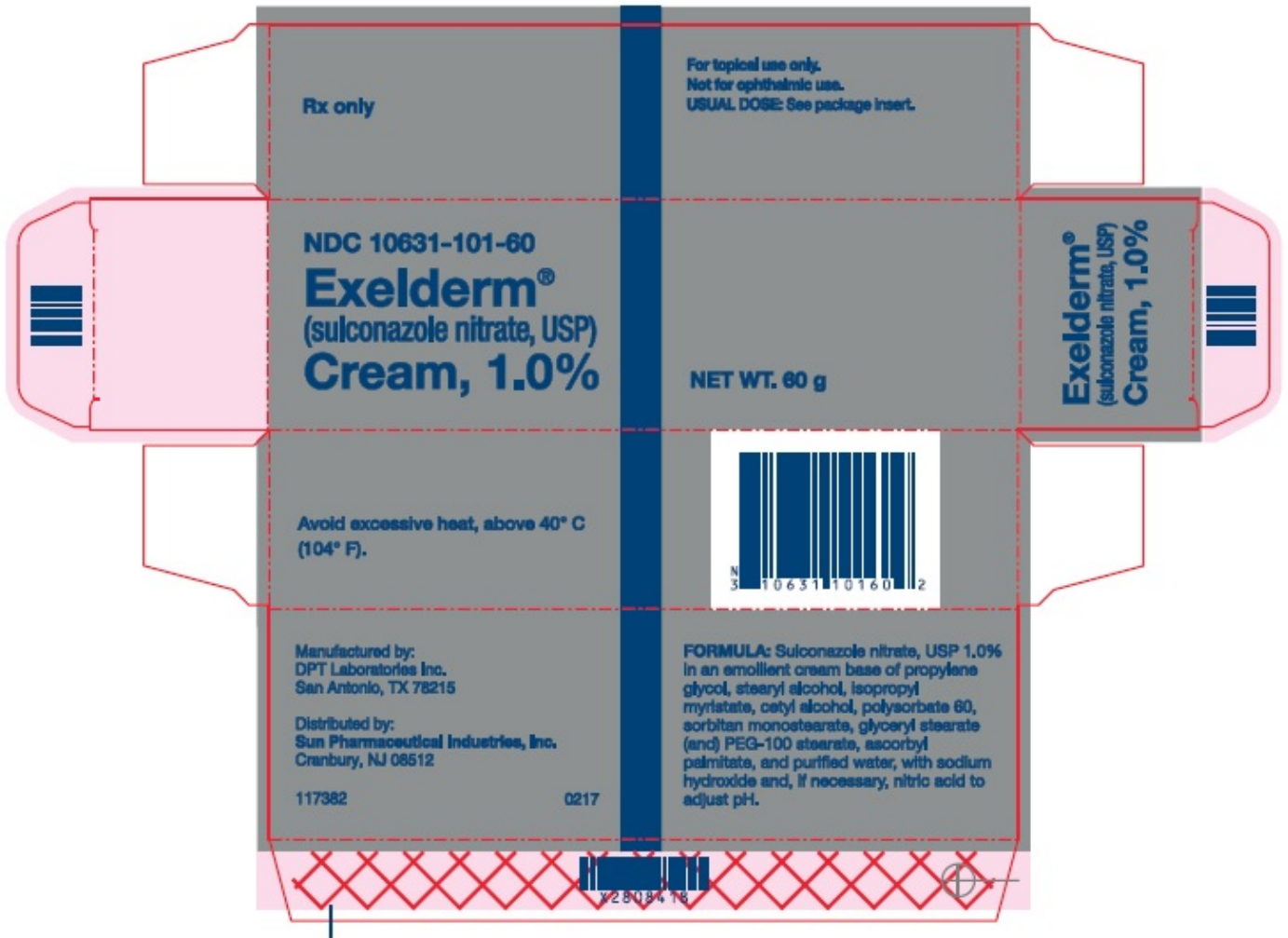
Manufactured by:
DPT Laboratories Inc.
San Antonio, TX 78215

Distributed by:
Sun Pharmaceutical
Industries, Inc.
Cranbury, NJ 08512

106716

0217

Exelderm Cream 60g Carton



EXELDERM

sulconazole nitrate cream

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:10631-101
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 g

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	

SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
WATER (UNII: 059QF0K00R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
NITRIC ACID (UNII: 411VRN1TV4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10631-101-15	15 g in 1 TUBE; Type 0: Not a Combination Product	02/01/2010	
2	NDC:10631-101-30	30 g in 1 TUBE; Type 0: Not a Combination Product	02/01/2010	
3	NDC:10631-101-60	60 g in 1 TUBE; Type 0: Not a Combination Product	02/01/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018737	02/01/2010	

Labeler - Sun Pharmaceutical Industries, Inc. (146974886)

Establishment

Name	Address	ID/FEI	Business Operations
Contract Pharmaceuticals Limited		248761249	MANUFACTURE(10631-101)

Establishment

Name	Address	ID/FEI	Business Operations
DPT Laboratories, Ltd.		832224526	ANALYSIS(10631-101) , MANUFACTURE(10631-101) , LABEL(10631-101) , PACK(10631-101)

Revised: 6/2018

Sun Pharmaceutical Industries, Inc.