SODIUM SULFACETAMIDE- sodium sulfacetamide liquid
Method Pharmaceuticals, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Sodium Sulfacetamide 10%

Inactive Ingredients

Butylated Hydroxytoluene, Citric Acid, Cetyl Alcohol, Cocamidopropyl Betaine, Disodium EDTA, Glycerin, Glyceryl Stearate SE, PEG-100 Stearate, Phenoxyethanol, Purified Water, Sodium Laureth Sulfate, Sodium Thiosulfate, Stearyl Alcohol, Triacetin, Xanthan Gum.

Description

Each gram contains 100 mg of sodium sulfacetamide in a vehicle consisting of: Butylated Hydroxytoluene, Citric Acid, Cetyl Alcohol, Cocamidopropyl Betaine, Disodium EDTA, Glycerin, Glyceryl Stearate SE, PEG-100 Stearate, Phenoxyethanol, Purified Water, Sodium Laureth Sulfate, Sodium Thiosulfate, Stearyl Alcohol, Triacetin, Xanthan Gum.

Indications

This product is intended for topical application in the following scaling dermatoses: seborrheic dermatitis and seborrhea sicca (dandruff). It also is indicated for the treatment of secondary bacterial infections of the skin due to organisms susceptible to sulfonamides.

Contraindications

This product is contraindicated in persons with known or suspected hypersensitivity to any of the ingredients of the product. This product is not to be used by patients with kidney disease.

Dosage and Administration

Seborrheic dermatitis including seborrhea sicca - Wash affected areas twice daily (morning and evening) or as directed by your physician. Avoid contact with eyes or mucous membranes. Wet skin and liberally apply to areas to be cleansed, massage gently into skin working into a full lather, rinse thoroughly, pat dry and repeat after 10 to 20 seconds. Rinsing with plain water will remove any excess medication. Repeat application as described above for 8 to 10 days or as directed by your physician. lf skin dryness occurs it may be controlled by rinsing cleanser off sooner or using less frequently. Regular shampooing following the use of this product is not necessary, but the hair should be shampooed at least once a week. As the condition subsides, the interval between

applications may be lengthened. Applications once or twice weekly or every other week may prevent recurrence. Should the condition recur after stopping therapy, the application of this product should be reinitiated as at the beginning of treatment.

Secondary cutaneous bacterial infections - Wash affected areas twice daily (morning and evening) or as directed by your physician. Avoid contact with eyes or mucous membranes. Wet skin and liberally apply to areas to be cleansed, massage gently into skin for 10 to 20 seconds working into a full lather, rinse thoroughly and pat dry. Rinsing with plain water will remove any excess medication. Repeat application as described above for 8 to 10 days or as directed by your physician. If skin dryness occurs it may be controlled by rinsing cleanser off sooner or using less frequently. See package insert for full prescribing information.

Warnings

WARNING: FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.
KEEP OUT OF REACH OF CHILDREN.

Avoid contact with eyes, lips and mucous membranes.

See label booklet for Full prescribing information.

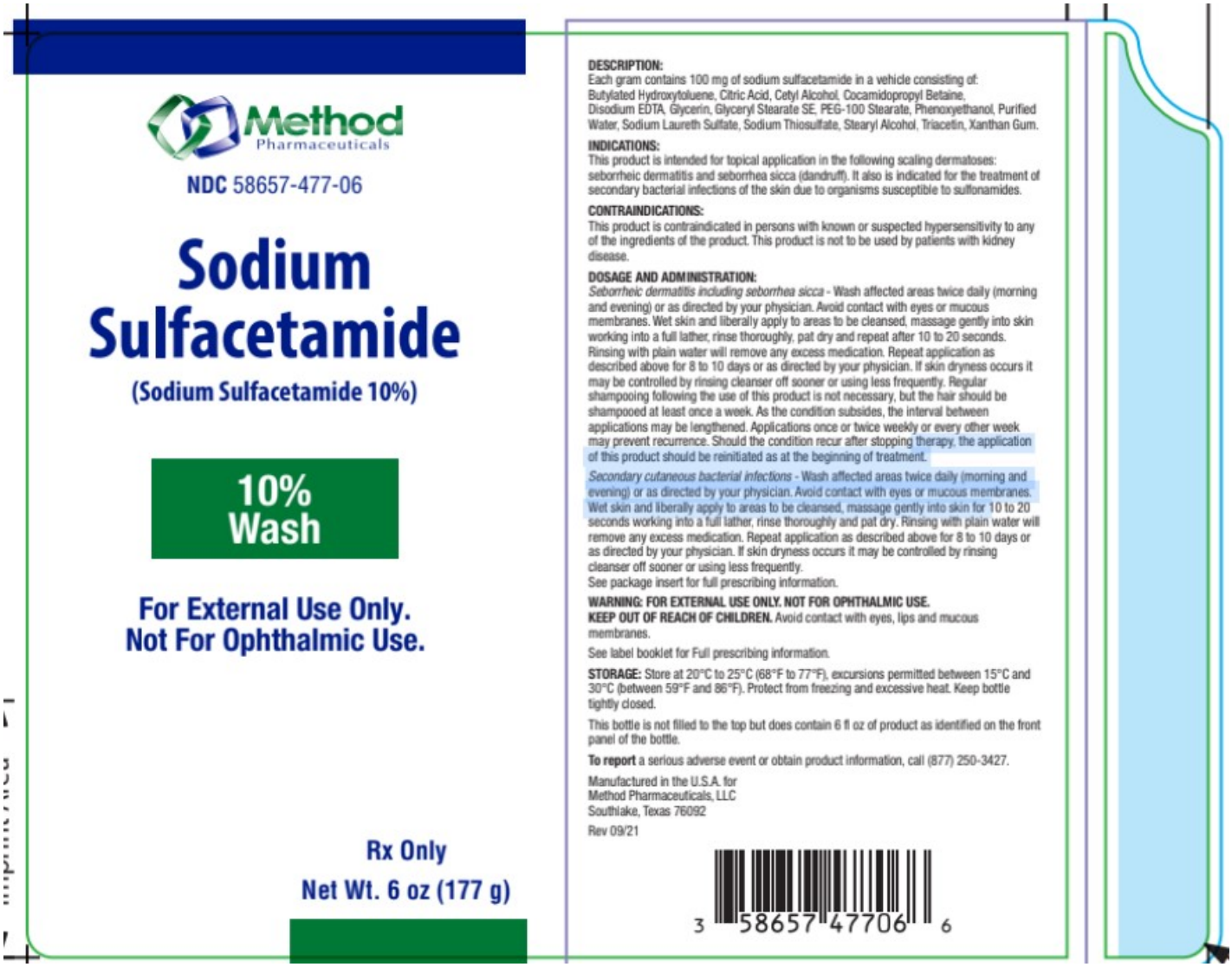
Storage

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Protect from freezing and excessive heat. Keep bottle tightly closed.

This bottle is not filled to the top but does contain 6 fl oz of product as identified on the front
panel of the bottle.

To report a serious adverse event or obtain product information, call (877) 250-3427.

Package



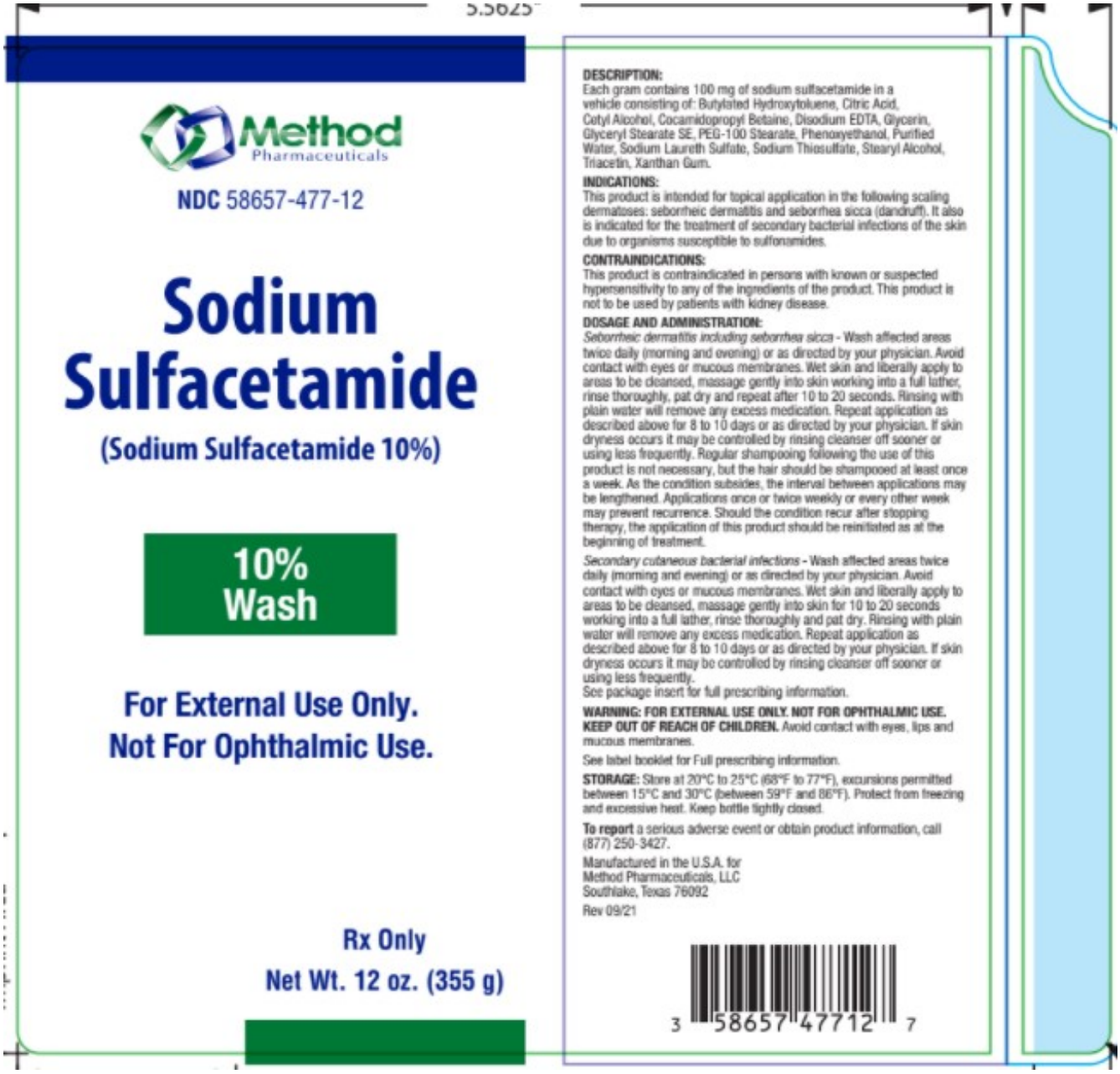
Manufactured in the U.S.A. for

Method Pharmaceuticals, LLC

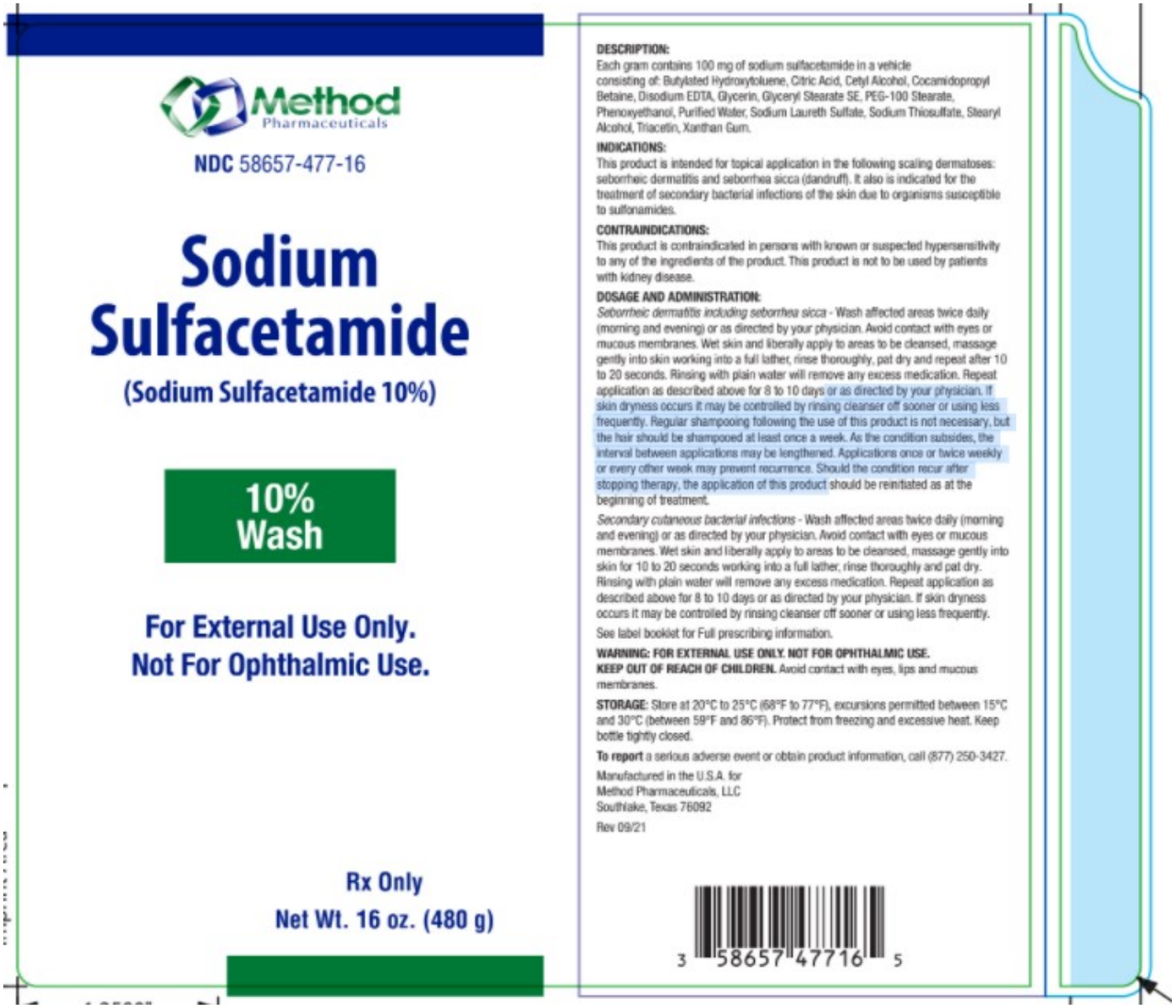
Southlake, Texas 76092

Rev 09/21

Package 12oz



Package 16 oz



SODIUM SULFACETAMIDE

sodium sulfacetamide liquid

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:58657-477
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SULFACETAMIDE SODIUM (UNII: 4NRT660KJQ) (SULFACETAMIDE - UNII:4965G3J0F5)	SULFACETAMIDE SODIUM	100 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**

GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
TRIACETIN (UNII: XHX3C3X673)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58657-477-12	355 g in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2022	
2	NDC:58657-477-16	480 g in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2022	
3	NDC:58657-477-06	177 g in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/15/2022	

Labeler - Method Pharmaceuticals, LLC (060216698)

Revised: 12/2023 Method Pharmaceuticals, LLC