EXACT-RX SODIUM SULFACETAMIDE WASH 10%- sodium sulfacetamide liquid
Exact-Rx, Inc.

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.

Exact-Rx Sodium Sulfacetamide Wash 10%

INDICATIONS: Sodium Sulfacetemide 10% Wash is intended for topical application in the following scaling dermatoses: seborrheic dermatisis and seborrhea sicca (dandruff). It also is indicated for the treatment of secondary bacterial infections of the skin due to organisms susceptible to sulfonamides.

DIRECTIONS FOR USE: Wash affected areas twice daily (morning and evening) or as directed by your physician. Rinse thoroughly and pat dry. **See package insert for complete product information**.

FOR EXTERNAL USE ONLY. NOT FOR INTRAVAGINAL OR OPHTHALMIC USE. (KEEP AWAY FROM EYES).

KEEP THIS AND ALL MEDICATION OUT OF REACH OF CHILDREN.

In case of accidental ingestion contact a poison control center immediately. Keep container tightly closed.

CONTRAINDICATIONS: Sodium Sulfacetamide 10% Wash is contraindicated in persons with know or suspected hypersensitivity to sulfonamides.

Each gram contains 100 mg of sodium sulfacetamide USP in a vehicle consisting of: citric acid, cocamidopropyl betaine, disodium EDTA, glyceryl stearate, methylparaben, PEG-6 caprylic/capric glycerides, PEG-60 almond glycerides, PEG-150 pentaerythrityl tetrastearate, polysorbate 60, purified water, sodium lauryl sulfate, sodium thiosulfate and xanthan gum.

Store at 25C (77F); excursions permitted to 15 to 30C (59 to 86F). See USP Controlled Room. Protect from freezing.

See bottle for lot number and expiration date

Manufactured in the U.S.A. for

Exact-Rx, Inc., Melville, NY 11747

SODIUM SULFACETAMIDE 10% WASH

(sodium sulfacetamide 10%)

Rx Only

FOR EXTERNAL USE ONLY.

NOT FOR OPHTHALMIC USE.

Description: Each gram contains 100 mg of sodium sulfacetamide USP in a vehicle consisting of: cocamidopropyl betaine, disodium EDTA, glyceryl stearate, methylparaben, PEG-6 caprylic/capric glycerides, PEG-60 almond glycerides, PEG-150 pentaerythrityl tetrastearate, polysorbate 60, purified water, sodium lauryl sulfate, and sodium thiosulfate.

HOW SUPPLIED: Sodium Sulfacetamide Wash 10% is available in a 6 fl oz (170 mL) bottle, NDC 42808-101-06, and in a 12 fl oz
(354.8 mL) bottle, NDC 42808-101-12.

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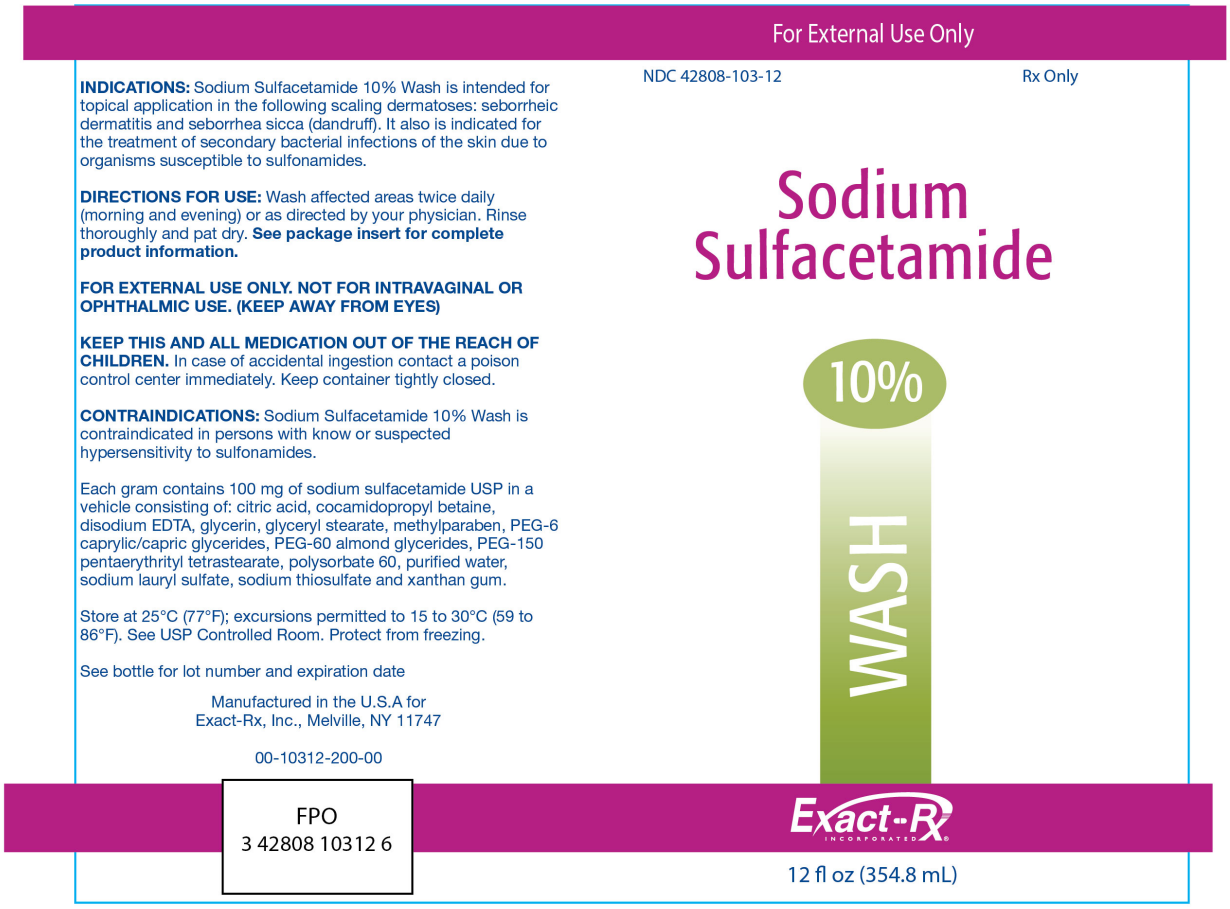
Iss:12/16



EXACT-RX SODIUM SULFACETAMIDE WASH 10%

sodium sulfacetamide liquid

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42808-103
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 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GLYCERIN (UNII: PDC6A3C0OX)	

GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PEG-6 CAPRYLIC/CAPRIC GLYCERIDES (UNII: GO50W2HWO8)	
PEG-60 ALMOND GLYCERIDES (UNII: 4Y0E651N0F)	
PEG-150 PENTAERYTHRITYL TETRASTEARATE (UNII: 8L4OOQ76AM)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42808-103-06	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2011	
2	NDC:42808-103-12	354.8 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/01/2011	

Labeler - Exact-Rx, Inc. (137953498)

Establishment

Name	Address	ID/FEI	Business Operations
Exact-Rx, Inc.		137953498	repack(42808-103)

Revised: 12/2019 Exact-Rx, Inc.