

## SUMADAN WASH- sulfacetamide sodium and sulfur cream

### SUMADAN- sulfacetamide sodium and sulfur

Medimetriks Pharmaceuticals 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.*

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#### Sumadan<sup>®</sup>

(Sodium Sulfacetamide 9% & Sulfur 4.5%)

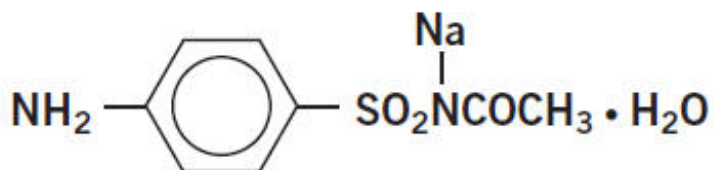
#### WASH

#### R<sub>x</sub> Only

In a Moisturizing  
Novasome<sup>®</sup> Vehicle

#### DESCRIPTION

Sodium sulfacetamide is a sulfonamide with antibacterial activity while sulfur acts as a keratolytic agent. Chemically sodium sulfacetamide is N-[(4-aminophenyl) sulfonyl]-acetamide, monosodium salt, monohydrate. The structural formula is:



Each mL of **Sumadan<sup>®</sup> (sodium sulfacetamide 9% & sulfur 4.5%) Wash** contains 90 mg of sodium sulfacetamide and 45 mg of sulfur in a formulation consisting of: butylated hydroxytoluene, C12-15 alkyl benzoate, caprylyl glycol, cetyl alcohol, cholesterol, chrysanthemum dendranthema, dimethicone, disodium oleamido MIPA sulfosuccinate, edetate disodium, ethylene brassilate, glyceryl stearate, hexylene glycol, lemon oil, magnesium aluminum silicate, magnesium chloride, magnesium nitrate, methylchloroisoithiazolinone, methylisothiazolinone, niacinamide, nonoxynol-20, octoxynol-5, purified water, PEG-100 stearate, phenoxyethanol, propylene glycol, sodium cocoyl isotheionite, sodium methyl cocoyl taurate, sodium thiosulfate, stearyl alcohol, xanthan gum.

#### CLINICAL PHARMACOLOGY

The most widely accepted mechanism of action of sulfonamides is the Woods-Fildes theory, which is based on the fact that sulfonamides act as competitive antagonists to para-aminobenzoic acid (PABA), an essential component for bacterial growth. While absorption through intact skin has not been determined, sodium sulfacetamide is readily absorbed from the gastrointestinal tract when taken orally and excreted in the urine, largely unchanged. The biological half-life has variously been reported as 7 to 12.8 hours. The exact mode of action of sulfur in the treatment of acne is unknown, but it has been reported that it inhibits the growth of *Propionibacterium acnes* and the formation of free fatty acids.

#### INDICATIONS

**Sumadan<sup>®</sup> (sodium sulfacetamide 9% & sulfur 4.5%) Wash** is indicated for the topical control of

acne vulgaris, acne rosacea and seborrheic dermatitis.

## CONTRAINDICATIONS

**Sumadan<sup>®</sup> (sodium sulfacetamide 9% & sulfur 4.5%) Wash** are contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. **Sumadan<sup>®</sup> (sodium sulfacetamide 9% & sulfur 4.5%) Wash** is not to be used by patients with kidney disease.

## WARNINGS

Although rare, sensitivity to sodium sulfacetamide may occur. Therefore, caution and careful supervision should be observed when prescribing this drug for patients who may be prone to hypersensitivity to topical sulfonamides. Systemic toxic reactions such as agranulocytosis, acute hemolytic anemia, purpura hemorrhagica, drug fever, jaundice, and contact dermatitis indicate hypersensitivity to sulfonamides. Particular caution should be employed if areas of denuded or abraded skin are involved.

**FOR EXTERNAL USE ONLY.** Keep away from eyes. Keep out of reach of children. Keep container tightly closed.

## PRECAUTIONS

### General

If irritation develops, use of the product should be discontinued and appropriate therapy instituted. Patients should be carefully observed for possible local irritation or sensitization during long-term therapy. The object of this therapy is to achieve desquamation without irritation, but sodium sulfacetamide and sulfur can cause reddening and scaling of the epidermis. These side effects are not unusual in the treatment of acne vulgaris, but patients should be cautioned about the possibility.

### Information for Patients

Avoid contact with eyes, eyelids, lips and mucous membranes. If accidental contact occurs, rinse with water. If excessive irritation develops, discontinue use and consult your physician.

### Carcinogenesis, Mutagenesis and Impairment of Fertility

Long-term studies in animals have not been performed to evaluate carcinogenic potential.

## PREGNANCY

Category C

Animal reproduction studies have not been conducted with **Sumadan<sup>®</sup> (sodium sulfacetamide 9% & sulfur 4.5%) Wash**. It is also not known whether **Sumadan<sup>®</sup> (sodium sulfacetamide 9% & sulfur 4.5%) Wash** can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. **Sumadan<sup>®</sup> (sodium sulfacetamide 9% & sulfur 4.5%) Wash** should be given to a pregnant woman only if clearly needed.

## NURSING MOTHERS

It is not known whether sodium sulfacetamide is excreted in the human milk following topical use of **Sumadan<sup>®</sup> (sodium sulfacetamide 9% & sulfur 4.5%) Wash**. However, small amounts of orally administered sulfonamides have been reported to be eliminated in human milk. In view of this and because many drugs are excreted in human milk, caution should be exercised when **Sumadan<sup>®</sup> (sodium sulfacetamide 9% & sulfur 4.5%) Wash** is administered to a nursing woman.

## **PEDIATRIC USE**

Safety and effectiveness in children under the age of 12 have not been established.

## **ADVERSE REACTIONS:**

Although rare, sodium sulfacetamide may cause local irritation.

## **DOSAGE AND ADMINISTRATION**

Apply **Sumadan<sup>®</sup> (sodium sulfacetamide 9% & sulfur 4.5%) Wash** once or twice daily to affected areas, or as directed by your physician. Wet skin and liberally apply to areas to be cleansed. Massage gently into skin for 10-20 seconds, working into a full lather, rinse thoroughly and pat dry. If drying occurs, it may be controlled by rinsing off **Sumadan<sup>®</sup> (sodium sulfacetamide 9% & sulfur 4.5%) Wash** sooner or using less often.

## **HOW SUPPLIED**

**Sumadan<sup>®</sup> (sodium sulfacetamide 9% & sulfur 4.5%) Wash** is available in a Net wt. 16 oz. (454 g) bottle, NDC 43538-190-16.

**Sumadan<sup>®</sup> KIT** contents one unit of **Sumadan<sup>®</sup> Wash**, Net wt. 16 oz. (454 g) and one unit of **Rehyla<sup>®</sup> Wash**, 16 oz. bottle, NDC 43538-191-16.

Store at controlled room temperature 15°- 30° C (59°- 86° F). Protect from freezing.

**KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.**

To report **SUSPECTED ADVERSE REACTIONS**, contact Medimetriks Pharmaceuticals, Inc., at 1-973-882-7512 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Manufactured for:

**MEDIMETRIKS  
PHARMACEUTICALS, INC.**

383 Route 46 West  
Fairfield, NJ 07004-2402 USA

[www.medimetriks.com](http://www.medimetriks.com)

IP022-R4  
Rev. 08/20

**PRINCIPAL DISPLAY PANEL - 454 g Bottle Carton**

NDC 43538-190-16

**R<sub>x</sub> Only**  
**Sumadan<sup>®</sup>**  
(Sodium Sulfacetamide 9% & Sulfur 4.5%)

**WASH**

**In a moisturizing  
Novasome<sup>®</sup> vehicle**

**Net Wt. 16 oz. (454 g)**

**MEDIMETRIKS  
PHARMACEUTICALS, INC.**



NDC 43538-190-16



Rx Only  
**Sumadan**<sup>®</sup>  
(Sodium Sulfacetamide 9% & Sulfur 4.5%)  
**WASH** In a Moisturizing  
Novasome<sup>®</sup> Vehicle



NDC 43538-190-16

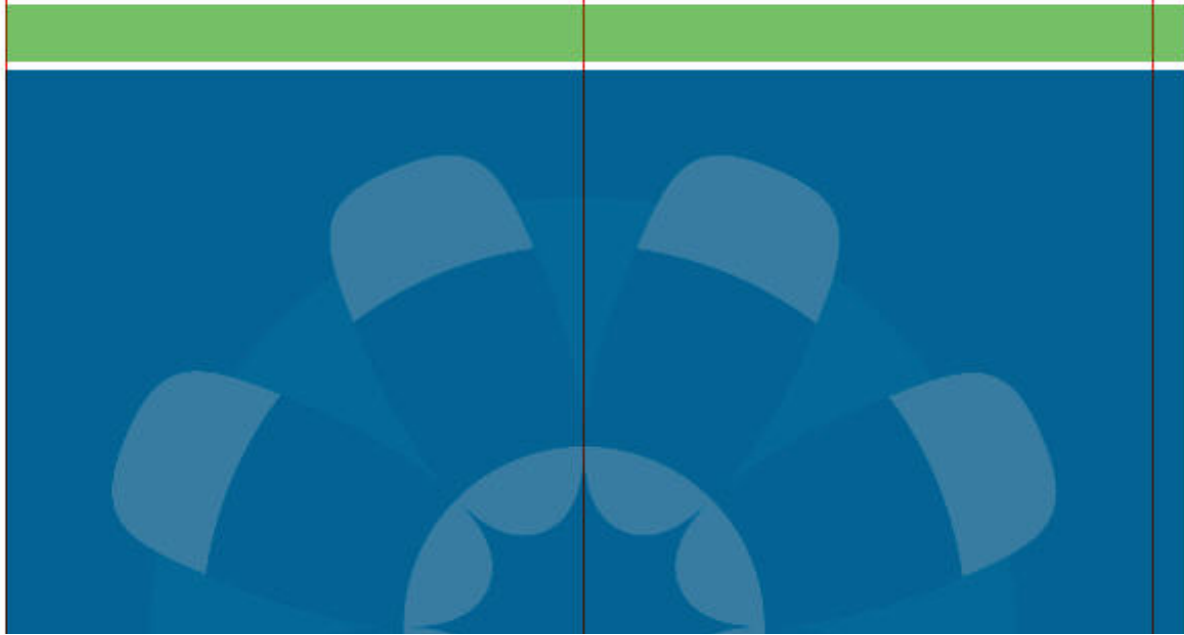


Rx Only  
**Sumadan**<sup>®</sup>  
(Sodium Sulfacetamide 9% & Sulfur 4.5%)  
**WASH** In a moisturizing  
Novasome<sup>®</sup> vehicle

NDC 43538-190-16



Rx Only  
**Sumadan**<sup>®</sup>  
(Sodium Sulfacetamide 9% & Sulfur 4.5%)  
**WASH** In a Moisturizing  
Novasome<sup>®</sup> Vehicle



Net Wt. 16 oz. (454 g)



Net Wt. 16 oz. (454 g)



NO COATH

**Rx Only**  
**Sumadan**<sup>®</sup>  
(Sodium Sulfacetamide 9% & Sulfur 4.5%)  
**WASH** In a Moisturizing  
Novasome<sup>®</sup> Vehicle

**INDICATIONS:** For the topical control of acne vulgaris, acne

NDC 43538-190-16

**Rx Only**  
**Sumadan**<sup>®</sup>

NG



NO COATING

rosacea and seborrheic dermatitis.

**DIRECTIONS:** Apply **SUMADAN® (9% sodium sulfacetamide & 4.5% sulfur) Wash** once or twice daily to affected areas, 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 10-20 seconds, working into a **full lather**, **rinse thoroughly** and pat dry. If drying occurs, it may be **controlled** by rinsing off **SUMADAN® Wash** sooner or using **less often**. See package insert for full Prescribing Information.

**FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.**

**Keep out of reach of children. Keep bottle tightly closed.**

**CONTRAINDICATIONS:** **SUMADAN® Wash** is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. **SUMADAN® Wash** is not to be used by patients with kidney diseases.

**INGREDIENTS:** Each gram of **SUMADAN® Wash** contains 90 mg of sodium sulfacetamide and 45 mg of sulfur in a formulation consisting of: butylated hydroxytoluene, C12-15 alkyl benzoate, caprylyl glycol, cetyl alcohol, cholesterol, chrysanthemum dendranthema, dimethicone, disodium oleamido MPA sulfosuccinate, edetate disodium, ethylene brassilate, glyceryl stearate, hexylene glycol, lemon oil, magnesium aluminum silicate, magnesium chloride, magnesium nitrate, methylchloroisothiazolinone, methylisothiazolinone, niacinamide, nonoxynol-20, octoxynol-5, purified water, PEG-100 stearate, phenoxyethanol, propylene glycol, sodium cocoyl isotheionite, sodium methyl cocoyl taurate, sodium thiosulfate, stearyl alcohol, xanthan gum.

Store at controlled room temperature 15°-30°C (59°-86°F). Protect from freezing.

For lot and expiration date, see bottom of carton.

Manufactured for:



383 Route 46 West • Fairfield, NJ 07004-2402 USA  
www.medimetriks.com



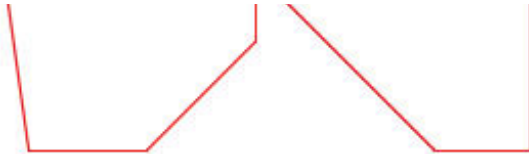
N 3 43538 19016 5 IC073-RI

# SUMADAN® (Sodium Sulfacetamide 9% & Sulfur 4.5%) WASH In a Moisturizing Novasome® Vehicle



Net Wt. 16 oz. (454 g)





**PRINCIPAL DISPLAY PANEL - Kit Carton**

NDC 43538-191-16

**R<sub>x</sub> Only**

**Sumadan<sup>®</sup>**

(Sodium Sulfacetamide 9% & Sulfur 4.5%)

***KIT***

**CONTENTS:**

1 - Sumadan<sup>®</sup> (Sodium Sulfacetamide 9% & Sulfur 4.5%) Wash (Net Wt. 16 oz.)

1- Rehya<sup>®</sup> Wash Moisturizing Daily Wash (16 fl. oz.)

**MEDIMETRIKS**

PHARMACEUTICALS, INC.



NDC 43538-191-16

Rx Only  
**Sumadan**<sup>®</sup>  
(Sodium Sulfacetamide 9% & Sulfur 4.5%)  
**KIT**

**CONTENTS:**

- 1 - Sumadan<sup>®</sup> (Sodium Sulfacetamide 9% & Sulfur 4.5%) Wash (Net Wt. 16 oz.)
- 1 - Rehya<sup>®</sup> Wash Moisturizing Daily Wash (16 fl. oz.)



NDC 43538-191-16

Rx Only  
**Sumadan**<sup>®</sup>  
(Sodium Sulfacetamide 9% & Sulfur 4.5%)  
**KIT**

**CONTENTS:**

- 1 - Sumadan<sup>®</sup> (Sodium Sulfacetamide 9% & Sulfur 4.5%) Wash (Net Wt. 16 oz.)
- 1 - Rehya<sup>®</sup> Wash Moisturizing Daily Wash (16 fl. oz.)

NDC 43538-191-16

Rx Only  
**Sumadan**<sup>®</sup>  
(Sodium Sulfacetamide 9% & Sulfur 4.5%)  
**KIT**

**CONTENTS:**

- 1 - Sumadan<sup>®</sup>  
(Sodium Sulfacetamide 9% & Sulfur 4.5%)  
Wash (Net Wt. 16 oz.)
- 1 - Rehya<sup>®</sup> Wash  
Moisturizing Daily Wash (16 fl. oz.)

NDC 43538-191-16

  
**Rx Only**  
**Sumadan**<sup>®</sup>  
(Sodium Sulfacetamide 9% & Sulfur 4.5%)  
**WASH** In a Moisturizing  
Novasome<sup>®</sup> Vehicle

**FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.**  
Keep out of reach of children. Keep bottle tightly closed.  
Store at controlled room temperature 15°-30°C (59°-86°F). Protect from freezing.

Manufactured for:  
Medimetrics Pharmaceuticals, Inc.  
383 Route 46 West, Fairfield, NJ 07004-2402 USA  
Made in USA

  
**REHYLA**<sup>®</sup>  
**WASH**

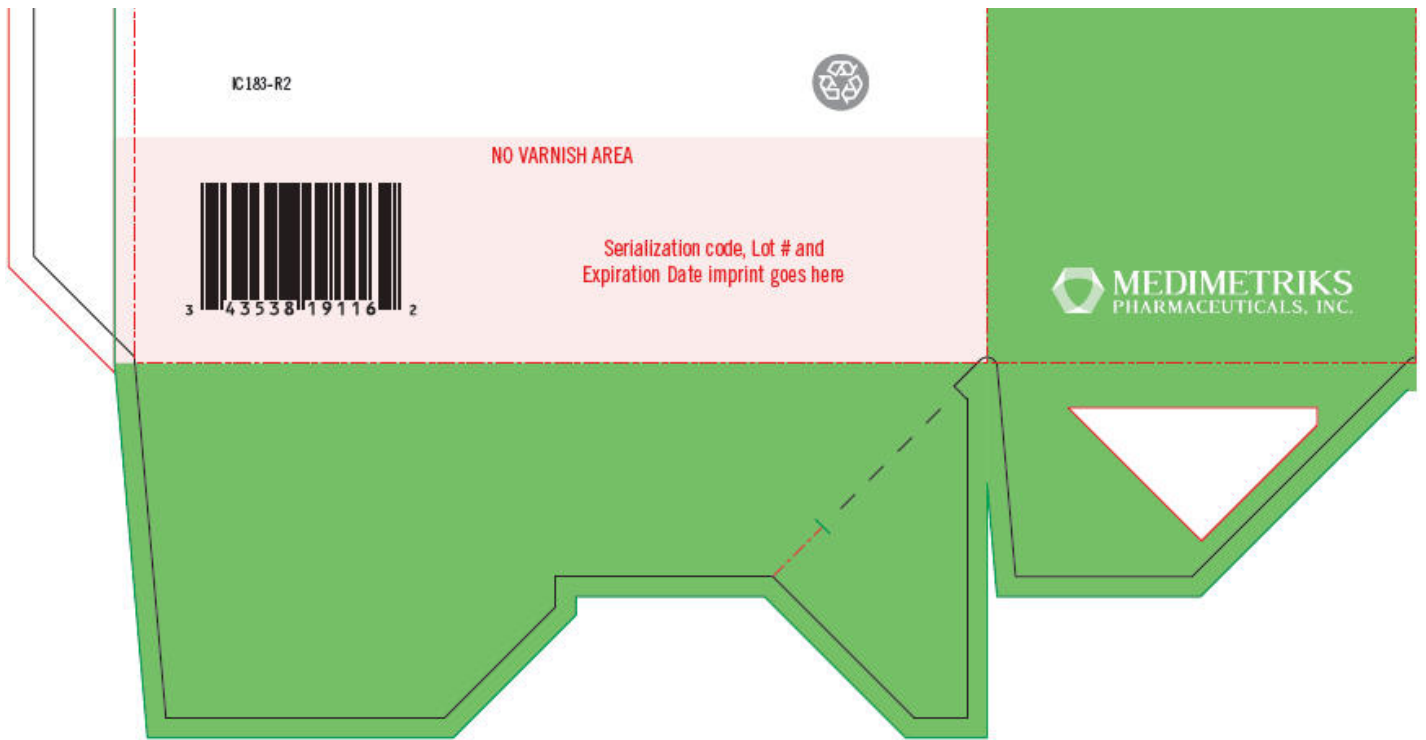
**CAUTION:** For external use only. Avoid contact with eyes, lips and mucous membranes.  
If contact occurs, rinse well with water. If rash or irritation develops, discontinue use.  
Keep out of reach of children.  
Store at room temperature between 15°-30°C (59°-86°F).

Manufactured for:  
Medimetrics Pharmaceuticals, Inc.  
383 Route 46 West, Fairfield, NJ 07004-2402 USA  
Made in USA

  
**Rx Only**  
**Sumadan**<sup>®</sup>  
(Sodium Sulfacetamide 9% & Sulfur 4.5%)  
**KIT**

**CONTENTS:**

- 1 - Sumadan<sup>®</sup>  
(Sodium Sulfacetamide 9% & Sulfur 4.5%)  
Wash (Net Wt. 16 oz.)
- 1 - Rehyla<sup>®</sup> Wash  
Moisturizing Daily Wash (16 fl. oz.)



## SUMADAN WASH

sulfacetamide sodium and sulfur cream

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:43538-190
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>sulfacetamide sodium</b> (UNII: 4NRT660KJQ) (sulfacetamide - UNII:4965G3J0F5)	sulfacetamide sodium	90 mg in 1 g
<b>sulfur</b> (UNII: 70FD1KFU70) (sulfur - UNII:70FD1KFU70)	sulfur	45 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>butylated hydroxytoluene</b> (UNII: 1P9D0Z171K)	
<b>Alkyl (C12-15) Benzoate</b> (UNII: A9EJ3J61HQ)	
<b>caprylyl glycol</b> (UNII: 00YIU5438U)	
<b>cetyl alcohol</b> (UNII: 936JST6JCN)	
<b>cholesterol</b> (UNII: 97C5T2UQ7J)	
<b>dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>edetate disodium</b> (UNII: 7FLD91C86K)	
<b>glyceryl monostearate</b> (UNII: 230OU9XXE4)	
<b>hexylene glycol</b> (UNII: KEH0A3F75J)	
<b>lemon oil</b> (UNII: I9GRO824LL)	
<b>magnesium aluminum silicate</b> (UNII: 6M3P64V0NC)	
<b>magnesium chloride</b> (UNII: 02F3473H9O)	

<b>magnesium nitrate</b> (UNII: 77CBG3UN78)	
<b>methylchloroisothiazolinone</b> (UNII: DEL7T5QRPN)	
<b>methylisothiazolinone</b> (UNII: 229D0E1QFA)	
<b>niacinamide</b> (UNII: 25X51I8RD4)	
<b>nonoxynol-20</b> (UNII: 60ZT1XYO5N)	
<b>octoxynol-5</b> (UNII: TJ327E1R1V)	
<b>water</b> (UNII: 059QF0K00R)	
<b>PEG-100 stearate</b> (UNII: YD01N1999R)	
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>propylene glycol</b> (UNII: 6DC9Q167V3)	
<b>sodium methyl cocoyl taurate</b> (UNII: JVL98CG53G)	
<b>sodium thiosulfate</b> (UNII: HX1032V43M)	
<b>stearyl alcohol</b> (UNII: 2KR89I4HIY)	
<b>xanthan gum</b> (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	YELLOW	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43538-190-16	1 in 1 CARTON	07/10/2011	
1		454 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		07/10/2011	

## SUMADAN

sulfacetamide sodium and sulfur kit

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:43538-191
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43538-191-16	1 in 1 CARTON; Type 0: Not a Combination Product	08/01/2011	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PUMP	454 g
Part 2	1 BOTTLE, PUMP	454 g

## Part 1 of 2

### SUMADAN WASH

sulfacetamide sodium and sulfur cream

## Product Information

Route of Administration TOPICAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sulfacetamide Sodium (UNII: 4NRT660KJQ) (Sulfacetamide - UNII:4965G3J0F5)	Sulfacetamide Sodium	90 mg in 1 g
Sulfur (UNII: 70FD1KFU70) (Sulfur - UNII:70FD1KFU70)	Sulfur	45 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
caprylyl glycol (UNII: 00YIU5438U)	
cetyl alcohol (UNII: 936JST6JCN)	
cholesterol (UNII: 97C5T2UQ7J)	
dimethicone (UNII: 92RU3N3Y1O)	
disodium oleamido mipa-sulfosuccinate (UNII: 0MBZ20845F)	
edetate disodium (UNII: 7FLD91C86K)	
glyceryl monostearate (UNII: 230OU9XXE4)	
hexylene glycol (UNII: KEH0A3F75J)	
lemon oil (UNII: I9GRO824LL)	
magnesium aluminum silicate (UNII: 6M3P64V0NC)	
magnesium chloride (UNII: 02F3473H9O)	
magnesium nitrate (UNII: 77CBG3UN78)	
methylchloroisothiazolinone (UNII: DEL7T5QRPN)	
methylisothiazolinone (UNII: 229D0E1QFA)	
niacinamide (UNII: 25X51I8RD4)	
nonoxynol-20 (UNII: 60ZT1XYO5N)	
octoxynol-5 (UNII: TJ327E1R1V)	
water (UNII: 059QF0KO0R)	
PEG-100 stearate (UNII: YD01N1999R)	
phenoxyethanol (UNII: HIE492ZZ3T)	
propylene glycol (UNII: 6DC9Q167V3)	

<b>sodium methyl cocoyl taurate</b> (UNII: JVL98CG53G)	
<b>sodium thiosulfate</b> (UNII: HX1032V43M)	
<b>stearyl alcohol</b> (UNII: 2KR89I4HIY)	
<b>xanthan gum</b> (UNII: TTV12P4NEE)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		454 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		06/01/2011	

### Part 2 of 2

## REHYLA WASH

moisturizing cream

### Product Information

<b>Route of Administration</b>	TOPICAL
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### Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	<b>water</b> (UNII: 059QF0K00R)	
INGR	<b>glyceryl monostearate</b> (UNII: 230OU9XXE4)	
INGR	<b>glycerin</b> (UNII: PDC6A3C0OX)	
INGR	<b>cetyl alcohol</b> (UNII: 936JST6JCN)	
INGR	<b>disodium oleamido mipa-sulfosuccinate</b> (UNII: 0MBZ20845F)	
INGR	<b>cholesterol</b> (UNII: 97C5T2UQ7J)	
INGR	<b>disodium laureth sulfosuccinate</b> (UNII: D6DH1DTN7E)	
INGR	<b>helianthus annuus seed wax</b> (UNII: 42DG15CHXV)	
INGR	<b>caprylyl glycol</b> (UNII: 00YIU5438U)	
INGR	<b>propylene glycol</b> (UNII: 6DC9Q167V3)	
INGR	<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	
INGR	<b>sodium cocoyl isethionate</b> (UNII: 518XTE8493)	
INGR	<b>cocamidopropyl betaine</b> (UNII: 5OCF3011KX)	
INGR	<b>sodium methyl cocoyl taurate</b> (UNII: JVL98CG53G)	
INGR	<b>C13-14 isoparaffin</b> (UNII: E4F12ROE70)	
INGR	<b>sodium chloride</b> (UNII: 451W47IQ8X)	
INGR	<b>niacinamide</b> (UNII: 25X51I8RD4)	
INGR	<b>edetate disodium</b> (UNII: 7FLD91C86K)	

INGR	<b>hexylene glycol</b> (UNII: KEH0A3F75J)	
INGR	<b>laureth-7</b> (UNII: Z95S6G8201)	
INGR	<b>chamaemelum nobile flower</b> (UNII: O2T154T6OG)	
INGR	<b>hyaluronate sodium</b> (UNII: YSE9PPT4TH)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		454 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		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** - Medimetriks Pharmaceuticals Inc. (019903816)

### Establishment

Name	Address	ID/FEI	Business Operations
IGI Laboratories		011036910	MANUFACTURE(43538-190, 43538-191)

Revised: 12/2020

Medimetriks Pharmaceuticals Inc.