SUMAXIN CLEANSING PADS- sulfacetamide sodium and sulfur cloth
SUMAXIN CP- 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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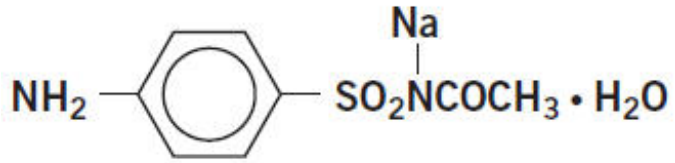
sumaxin®
(sodium sulfacetamide 10% & sulfur 4%)
Cleansing Pads

In a vehicle containing Green Tea & Aloe

R_x Only

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 pad of **Sumaxin® (sodium sulfacetamide 10% & sulfur 4%) Cleansing Pads** is coated with a cleanser-based formulation. Each gram of this cleanser-based formulation contains 100 mg of Sodium Sulfacetamide and 40 mg of Sulfur. The cleanser base consists of: aloe, butylated hydroxytoluene, cetyl alcohol, disodium oleamido MEA sulfosuccinate, edetate disodium, fragrance, glycerin, glyceryl stearate/PEG-100 stearate, green tea, methylparaben, propylparaben, purified water, sodium cocoyl isethionate, sodium lauryl sulfoacetate, sodium thiosulfate, stearyl alcohol.

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

Sumaxin® (sodium sulfacetamide 10% & sulfur 4%) Cleansing Pads are indicated in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS

Sumaxin® (sodium sulfacetamide 10% & sulfur 4%) Cleansing Pads are contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. **Sumaxin® (sodium sulfacetamide 10% & sulfur 4%) Cleansing Pads** are 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 **Sumaxin® (sodium sulfacetamide 10% & sulfur 4%) Cleansing Pads**. It is also not known whether **Sumaxin® (sodium sulfacetamide 10% & sulfur 4%) Cleansing Pads** can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. **Sumaxin® (sodium sulfacetamide 10% & sulfur 4%) Cleansing Pads** 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 **Sumaxin® (sodium sulfacetamide 10% & sulfur 4%) Cleansing Pads**. 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 **Sumaxin® (sodium sulfacetamide 10% & sulfur 4%) Cleansing Pads** are 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

Wash affected area(s) with cleansing pad once or twice daily, or as directed by your physician. Wet area(s) with water. Wet pad with a little water and work into a full lather. Cleanse area(s) with pad for 10-20 seconds, avoiding eyes. Rinse thoroughly and pat dry. Discard pad. Do not flush.

HOW SUPPLIED

Sumaxin® (sodium sulfacetamide 10% & sulfur 4%) Cleansing Pads are available in boxes of 60 cloths (3.7 g), NDC 43538-100-60.

Store at 15°-30° C (59°-86° F).

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.

Manufactured for:
MEDIMETRIKS
PHARMACEUTICALS, INC.

383 Route 46 West
Fairfield, NJ 07004-2402 USA

www.medimetriks.com

IP001-R5
Rev. 10/17

PRINCIPAL DISPLAY PANEL - 60 Pad Carton

NDC 43538-100-60

R_x Only
sumaxin®
(sodium sulfacetamide 10% & sulfur 4%)
Cleansing Pads

In a vehicle containing Green Tea & Aloe

60 Cleansing Pads
Net wt. 3.7 g Each

MEDIMETRIKS
PHARMACEUTICALS, INC.

NDC 43538-100-60

Rx Only

sumaxin®

(sodium sulfacetamide 10% & sulfur 4%)

Cleansing Pads

In a vehicle containing Green Tea & Aloe

MEDIMETRIKS
PHARMACEUTICALS, INC.

NDC 43538-100-60

Rx Only

sumaxin®

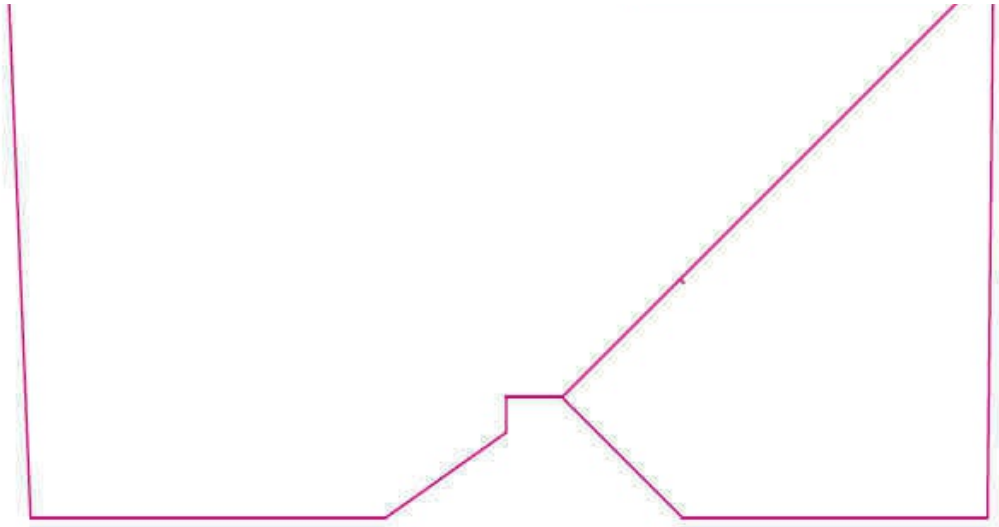
(sodium sulfacetamide 10% & sulfur 4%)

Cleansing Pads

In a vehicle containing Green Tea & Aloe

60 Cleansing Pads
Net wt. 3.7 g Each

MEDIMETRIKS
PHARMACEUTICALS, INC.



NDC 43538-100-60

Rx Only

sumaxin®

(sodium sulfacetamide 10% & sulfur 4%)

Cleansing Pads

In a vehicle containing Green Tea & Aloe

60 Cleansing Pads
Net wt. 3.7 g Each

MEDIMETRIKS
PHARMACEUTICALS, INC.

Rx Only

sumaxin®

(sodium sulfacetamide 10% & sulfur 4%)

Cleansing Pads

NDC 43538-100-60

In a vehicle containing Green Tea & Aloe

INDICATIONS: For the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis. See package insert for full prescribing information.

DIRECTIONS: Wash affected areas with **SUMAXIN® Cleansing Pads** once or twice daily, or as directed by your physician.

1. Wet affected areas with water.
2. Wet **SUMAXIN® Cleansing Pad** with water and work into a full lather.
3. Cleanse face with **SUMAXIN® Cleansing Pad** for 10-20 seconds, avoiding eyes.
4. Rinse thoroughly and pat dry.
5. Discard Pad. Do not flush.

WARNINGS: FOR EXTERNAL USE ONLY. Keep away from eyes. Keep out of reach of children.

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

CONTENTS: ACTIVE INGREDIENTS: Sodium sulfacetamide 10% and sulfur 4%. **OTHER INGREDIENTS:** aloe, butylated hydroxytoluene, cetyl alcohol, disodium oleamido MEA sulfosuccinate, edetate disodium, fragrance, glycerin, glyceryl stearate/PEG-100 stearate, green tea, methylparaben, propylparaben, purified water, sodium cocoyl isethionate, sodium lauryl sulfoacetate, sodium thiosulfate, stearyl alcohol.

Store at 15°-30° C (59°-86° F).

Manufactured for:

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IC003-R4

3 43538 10060 7

NDC 43538-100-60

Rx Only

sumaxin®

(sodium sulfacetamide 10% & sulfur 4%)

Cleansing Pads

In a vehicle containing Green Tea & Aloe

60 Cleansing Pads
Net wt. 3.7 g Each

MEDIMETRIKS
PHARMACEUTICALS, INC.

PRINCIPAL DISPLAY PANEL - Kit Carton

NDC 43538-101-60

R_x Only
sumaxin®
(Sodium Sulfacetamide 10%
& Sulfur 4%) Cleansing Pads
CP
KIT

CONTENTS:

1 - Sumaxin® (Sodium Sulfacemide 10% & Sulfur 4%) Cleansing Pads Carton - 60 Pads (Net wt. 3.7 g each)
1 - Rehyla® Wash Moisturizing Daily Wash (16 fl. oz.)

MEDIMETRIKS
PHARMACEUTICALS, INC.

NDC 43538-101-60

Rx Only

sumaxin® CP KIT

(Sodium Sulfacetamide 10% & Sulfur 4%) Cleansing Pads

CONTENTS:

1 - Sumaxin® (Sodium Sulfacetamide 10% & Sulfur 4%) Cleansing Pads Carton - 60 Pads (Net wt. 3.7 g each)

1 - Rehyla® Wash Moisturizing Daily Wash (16 fl. oz.)

MEDIMETRIKS PHARMACEUTICALS, INC.

NDC 43538-101-60

Rx Only

sumaxin® CP KIT

(Sodium Sulfacetamide 10% & Sulfur 4%) Cleansing Pads

CONTENTS:

1 - Sumaxin® (Sodium Sulfacetamide 10% & Sulfur 4%) Cleansing Pads Carton - 60 Pads (Net wt. 3.7 g each)

1 - Rehyla® Wash Moisturizing Daily Wash (16 fl. oz.)

MEDIMETRIKS PHARMACEUTICALS, INC.

NDC 43538-101-60

Rx Only

sumaxin®

(sodium sulfacetamide 10% & sulfur 4%)

Cleansing Pads

In a vehicle containing Green Tea & Aloe

Manufactured for: Medimetriks Pharmaceuticals, Inc.
383 Route 46 West, Fairfield, NJ 07004 • 973-882-7512 • www.medimetriks.com

REHYLA® WASH

Manufactured for: Medimetriks Pharmaceuticals, Inc.
383 Route 46 West, Fairfield, NJ 07004 • 973-882-7512 • www.medimetriks.com

NO VARNISH AREA

Sterilization code, LOT and Expiration Date imprint goes here

IC085-R2

NDC 43538-101-60

Rx Only

sumaxin® CP KIT

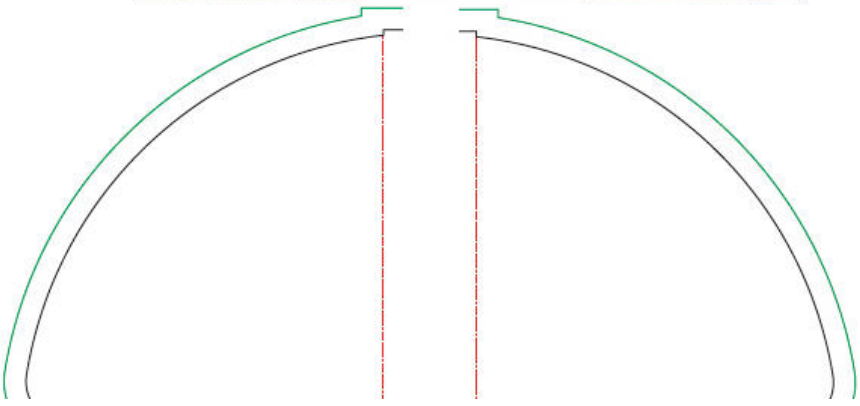
(Sodium Sulfacetamide 10% & Sulfur 4%) Cleansing Pads

CONTENTS:

1 - Sumaxin® (Sodium Sulfacetamide 10% & Sulfur 4%) Cleansing Pads Carton - 60 Pads (Net wt. 3.7 g each)

1 - Rehyla® Wash Moisturizing Daily Wash (16 fl. oz.)

MEDIMETRIKS PHARMACEUTICALS, INC.



Rx Only

sumaxin®

(sodium sulfacetamide 10% & sulfur 4%)

Cleansing Pads

In a water soluble cleansing gel with Green Tea & Aloe

INDICATIONS: For the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis. See package insert for full prescribing information.

DIRECTIONS: Wash affected areas with **SUMAXIN® Cleansing Pads** once or twice daily, or as directed by your physician.

1. Wet affected areas with water.
2. Wet **SUMAXIN® Cleansing Pad** with water and work into a full lather.
3. Cleanse face with **SUMAXIN® Cleansing Pad** for 10-20 seconds, avoiding eyes.
4. Rinse thoroughly and pat dry.
5. Discard Pad. Do not flush.

WARNINGS: FOR EXTERNAL USE ONLY. Keep away from eyes. Keep out of reach of children.

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

REHYLA® 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).

NDC 43538-101-60

Rx Only

sumaxin® CP KIT

(Sodium Sulfacetamide 10% & Sulfur 4%) Cleansing Pads

CONTENTS:

1 - Sumaxin® (Sodium Sulfacetamide 10% & Sulfur 4%) Cleansing Pads Carton - 60 Pads (Net wt. 37 g each)

1 - Rehyla® Wash Moisturizing Daily Wash (16 fl. oz.)

MEDIMETRIKS PHARMACEUTICALS, INC.

NDC 43538-101-60

Rx Only

sumaxin® CP KIT

(Sodium Sulfacetamide 10% & Sulfur 4%) Cleansing Pads

CONTENTS:

1 - Sumaxin® (Sodium Sulfacetamide 10% & Sulfur 4%) Cleansing Pads Carton - 60 Pads (Net wt. 37 g each)

1 - Rehyla® Wash Moisturizing Daily Wash (16 fl. oz.)

MEDIMETRIKS PHARMACEUTICALS, INC.

SUMAXIN CLEANSING PADS

sulfacetamide sodium and sulfur cloth

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:43538-100
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
Sulfur (UNII: 70FD1KFU70) (sulfur - UNII:70FD1KFU70)	Sulfur	40 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
aloe (UNII: V5VD430YW9)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
cetyl alcohol (UNII: 936JST6JCN)	
disodium oleamido monoethanolamine sulfosuccinate (UNII: 5M1101WGSY)	
edetate disodium (UNII: 7FLD91C86K)	
glycerin (UNII: PDC6A3C0OX)	
green tea leaf (UNII: W2ZU1RY8B0)	
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
sodium cocoyl isethionate (UNII: 518XTE8493)	
sodium lauryl sulfoacetate (UNII: D0Y70F2B9J)	
sodium thiosulfate (UNII: HX1032V43M)	
stearyl alcohol (UNII: 2KR89I4H1Y)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:43538-100-60	60 in 1 CARTON	01/01/2009	
1		3.7 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/01/2009	

SUMAXIN CP

sulfacetamide sodium and sulfur kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:43538-101

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:43538-101-60	1 in 1 CARTON	08/01/2011	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	60 PACKET	222 g
Part 2	1 BOTTLE, PUMP	454 g

Part 1 of 2

SUMAXIN CLEANSING PADS

sulfacetamide sodium and sulfur cloth

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	100 mg in 1 g
sulfur (UNII: 70FD1KFU70) (sulfur - UNII:70FD1KFU70)	sulfur	40 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
aloe (UNII: V5VD430YW9)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
cetyl alcohol (UNII: 936JST6JCN)	
disodium oleamido monoethanolamine sulfosuccinate (UNII: 5M1101WGSY)	
edetate disodium (UNII: 7FLD91C86K)	
glycerin (UNII: PDC6A3C0OX)	
green tea leaf (UNII: W2ZU1RY8B0)	
methylparaben (UNII: A2I8C7HI9T)	

propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
sodium cocoyl isethionate (UNII: 518XTE8493)	
sodium lauryl sulfoacetate (UNII: D0Y70F2B9J)	
sodium thiosulfate (UNII: HX1032V43M)	
stearyl alcohol (UNII: 2KR89I4H1Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		60 in 1 CARTON		
1		3.7 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		01/01/2009	

Part 2 of 2

REHYLA WASH

bath soaps and body washes [personal cleanliness]

Product Information

Route of Administration	TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	**water** (UNII: 059QF0KO0R)	
INGR	**glyceryl monostearate** (UNII: 230OU9XXE4)	
INGR	**glycerin** (UNII: PDC6A3C0OX)	
INGR	**cetyl alcohol** (UNII: 936JST6JCN)	
INGR	**disodium oleamido mipa-sulfosuccinate** (UNII: 0MBZ20845F)	
INGR	**cholesterol** (UNII: 97C5T2UQ7J)	
INGR	**disodium laureth sulfosuccinate** (UNII: D6DH1DTN7E)	
INGR	**helianthus annuus seed wax** (UNII: 42DG15CHXV)	
INGR	**caprylyl glycol** (UNII: 00YIU5438U)	
INGR	**propylene glycol** (UNII: 6DC9Q167V3)	
INGR	**phenoxyethanol** (UNII: HIE492ZZ3T)	
INGR	**sodium cocoyl isethionate** (UNII: 518XTE8493)	
INGR	**cocamidopropyl betaine** (UNII: 5OCF3O11KX)	

INGR	**sodium methyl cocoyl taurate** (UNII: JVL98CG53G)	
INGR	**C13-14 isoparaffin** (UNII: E4F12ROE70)	
INGR	**sodium chloride** (UNII: 451W47IQ8X)	
INGR	**niacinamide** (UNII: 25X51I8RD4)	
INGR	**edetate disodium** (UNII: 7FLD91C86K)	
INGR	**hexylene glycol** (UNII: KEH0A3F75J)	
INGR	**laureth-7** (UNII: Z95S6G8201)	
INGR	**chamaemelum nobile flower** (UNII: O2T154T6OG)	
INGR	**hyaluronate sodium** (UNII: YSE9PPT4TH)	

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
Marketing Advertising Promotions, Inc.		797063526	PACK(43538-101)

Revised: 12/2023 Medimetriks Pharmaceuticals, Inc.