SODIUM SULFACETAMIDE- sodium sulfacetamide solution
E. FOUGERA & Co., A division of Nycomed US 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.

SODIUM SULFACETAMIDE Medicated Pads 10%

in a Urea Vehicle

FOR DERMATOLOGIC USE ONLY

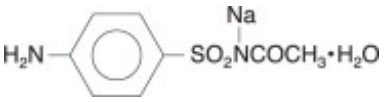
Rx only

NOT FOR OPHTHALMIC USE

DESCRIPTION:

Sodium Sulfacetamide Medicated Pads 10% contain a 10% solution of sodium sulfacetamide on a textured pad. Each gram of medicated solution contains 100 mg sodium sulfacetamide, purified water, sodium EDTA, sodium thiosulfate and urea (1 0%). **Sodium Sulfacetamide Medicated Pads** are greaseless and leave no residue when applied to the skin.

Sodium sulfacetamide is a sulfonamide with antibacterial activity. Chemically, sodium sulfacetamide is $C_8H_9N_2Na0_3S•H_2O$, with a molecular weight of 254.24. Chemically it is acetamide, N- [(4 aminophenyl) sulfonyl]-, monosodium salt and monohydrate, with the following structural formula:



CLINICAL PHARMACOLOGY:

Sodium sulfacetamide exerts a bacteriostatic effect against sulfonamide-sensitive gram-positive and gram-negative micro-organism including *P. acne* commonly isolasted from secondary cutaneous pyogenic infections.

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 P (ABA), an essential component for bacterial growth. While absorption through intact skin in humans 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 o t 12.8 hours.

INDICATIONS AND USAGE:

Sodium Sulfacetamide Medicated Pads are indicated in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS:

Sodium Sulfacetamide Medicated Pads are contraindicated in persons with known or suspected hypersensitivity to sulfonamides or to any of the ingredients of the preparation. **Sodium Sulfacetamide Medicated Pads** are not to be used by patients with kidney disease.

WARNINGS:

Although rare, sensitivity t o 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. Sulfonamides are known to cause Stevens-Johnson syndrome in hypersensitive individuals. Stevens-Johnson syndrome also has been reported following the use of sodium sulfacetamide topically. Cases of drug-induced systemic lupus erythematosus from topical sulfacetamide also have been reported.

PRECAUTIONS:

General: Nonsusceptible organisms, including fungi, may proliferate with the use of this preparation. Hypersensitivity reactions may recur when a sulfonamide is readministered, irrrespective of the route of administration, and cross hypersensitivity between different sulfonamides may occur. If **Sodium Sulfacetamide Medicated Pads** produce signs of hypersensitivity or other untoward reactions, discontinue use of the preparation. Systemic absorption of topical sulfonamides is greater following application to large, infected, abraded, denuded, or severely burned areas. Under these circumstances, potentially any of the adverse effects produced by the systemic administration of these agents could occur, and appropriate observations and laboratory determinations should be performed.

INFORMATION FOR PATIENTS:

Avoid contact with eyes, eyelids, lips and mucous membranes. If accidental contact occurs, rinse with water. Patients should discontinue the use of **Sodium Sulfacetamide Medicated Pads** if the condition becomes worse, or if a rash develops in the area being treated or elsewhere. **Sodium Sulfacetamide Medicated Pads** also should be discontinued promptly and the physician notified if any arthritis, fever, or sores in the mouth develop.

Drug Interactions: **Sodium Sulfacetamide Medicated Pads** are incompatible with silver preparations.

Carcinogenesis, Mutagenesis, and Impairment of Fertility: Long-term animal studies for carcinogenic potential have not been performed on **Sodium Sulfacetamide Medicated Pads**.

Pregnancy Category C: Animal reproduction studies have not been conducted with **Sodium Sulfacetamide Medicated Pads**. It also is not known whether **Sodium Sulfacetamide Medicated Pads** can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. **Sodium Sulfacetamide Medicated Pads** should be used by a pregnant woman only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk following topical use of **Sodium Sulfacetamide Medicated Pads**. Because many drugs are excreted in human milk, caution should be exercised when **Sodium Sulfacetamide Medicated Pads** are administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children below the age of 12 years have not been established.

ADVERSE REACTIONS:

Reports of irritation and hypersensitivity to sodium sulfacetamide are uncommon. The following adverse reactions, reported after administration of sterile ophthalmic sodium sulfacetamide, are noteworthy: instances of Stevens-Johnson syndrome and instances of local hypersensitivity, which progressed to a syndrome resembling systemic lupus erythematosus; in one case a fatal outcome has been reported (see **WARNINGS**).

DOSAGE AND ADMINISTRATION:

Gently apply **Sodium Sulfacetamide Medicated Pads** to the affected areas 1 to 2 times daily or as directed by a physician until the infection has cleared.

HOW SUPPLIED:

Sodium Sulfacetamide Medicated Pads NDC 0168-0484-01 contain 30 Foil Pouches, each with a single-use medicated pad (2.5 mL each).

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

Sodium Sulfacetamide Medicated Pads may darken after prolonged storage. Slight discoloration does not impair the efficacy or safety of the product.

Manufactured for: E. FOUGERA & CO.
A division of Nycomed US Inc., Melville New York 11747
Manufactured by: Pegasus Laboratories, Inc., Pensacola, FL 32514

IL302A R3/09

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – CARTON – 30 CT

NDC 0168-0484-01

30 Foil Pouches (2.5 mL each)

Fougera®

SODIUM SULFACETAMIDE

Medicated Pads 10%

In a Urea Vehicle

For Topical Use Only

For dermatologic use only – not for ophthalmic use

Contains: 30 Foil Pouches, each with a single-use medicated pad (2.5 mL each)

Rx only

E. FOUGERA & CO.

A division of Nycomed US Inc.

Melville, New York 11747

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – CONTAINER – 2.5 mL

NDC 0168-0484-01

2.5 mL

Fougera®

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Single-use medicated pad 2.5 mL

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NDC 0168-0484-01 2.5 mL

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Medicated Pads 10%
in a Urea Vehicle
For Topical Use Only
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Single-use medicated pad 2.5 mL

℞ only

E. FOUGERA & CO.
A division of Nycomed US Inc.
Melville, New York 11747

DIRECTIONS: Use only as directed by a physician.

CAUTION: If redness or irritation occurs, discontinue use.

PLEASE SEE PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION INCLUDING LIST OF INGREDIENTS.

For external use only. Not for ophthalmic use.
KEEP OUT OF REACH OF CHILDREN.

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

Mfd. for: E. FOUGERA & CO.
A division of Nycomed US Inc.
Melville, New York 11747

Mfd. by: Pegasus Laboratories, Inc.
Pensacola, FL 32514

XM301A R9/09

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SODIUM SULFACETAMIDE

sodium sulfacetamide solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0168-0484
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**
water (UNII: 059QF0KO0R)	
sodium thiosulfate (UNII: HX1032V43M)	
urea (UNII: 8W8T17847W)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0168-0484-01	30 in 1 CARTON		
1		1 in 1 POUCH		
1		1 g in 1 APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		03/12/2010	

Labeler - E. FOUGERA & Co., A division of Nycomed US Inc. (043838424)

Registrant - Nycomed US Inc. (043838424)

Revised: 3/2010 E. FOUGERA & Co., A division of Nycomed US Inc.