

PLEXION
(sodium sulfacetamide 10% and sulfur 5%)
Cleanser

PLEXION
(sodium sulfacetamide 10% and sulfur 5%)
Cleansing Cloths

PLEXION^{TS}
(sodium sulfacetamide 10% and sulfur 5%)
Topical Suspension

PLEXION^{SCT}
(sodium sulfacetamide 10% and sulfur 5%)

Each gram of PLEXION^{SCT} (sodium sulfacetamide USP 10% and sulfur USP 5%) contains 100 mg of Sodium Sulfacetamide USP and 50 mg of Sulfur USP in a cream containing: Purified Water USP, Kaolin USP, Glyceryl Stearate (and) PEG-100 Stearate, Witch Hazel USP, Silicon Dioxide, Magnesium Aluminum Silicate, Benzyl Alcohol NF, Water (and) Propylene Glycol (and) Quillaja Saponaria Extract, Xanthan Gum NF, Sodium Thiosulfate USP, Fragrance.

Each gram of PLEXION^{TS} (sodium sulfacetamide USP 10% and sulfur USP 5%) Topical Suspension contains 100 mg of Sodium Sulfacetamide USP and 50 mg of Sulfur USP in a suspension containing: Purified Water USP, Propylene Glycol USP, Isopropyl Myristate NF, Light Mineral Oil NF, Polysorbate 60, Sorbitan Monostearate NF, Cetyl Alcohol NF, Hydrogenated Coco-Glycerides, Stearyl Alcohol NF, Fragrances, Benzyl Alcohol NF, Glyceryl Stearate (and) PEG-100 Stearate, Dimethicone NF, Zinc Ricinoleate, Xanthan Gum NF, Edetate Disodium USP, and Sodium Thiosulfate USP.

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:

PLEXION^{TS} Cleanser, PLEXION^{TS} Cleansing Cloths, PLEXION^{SCT} and PLEXION^{TS} are indicated in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS:

PLEXION^{TS} Cleanser, PLEXION^{TS} Cleansing Cloths, PLEXION^{SCT} and PLEXION^{TS} are contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. These PLEXION brand products are not to be used by patients with kidney disease.

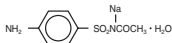
WARNINGS:

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

Rx 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 gram of PLEXION^{TS} (sodium sulfacetamide USP 10% and sulfur USP 5%) Cleanser contains 100 mg of Sodium Sulfacetamide USP and 50 mg of Sulfur USP in a cleanser base containing: Purified Water USP, Sodium Methyl Oleoyl Taurate, Sodium Cocoyl Isethionate, Disodium Oleamide MEA Sulfosuccinate, Cetyl Alcohol NF, Glyceryl Stearate (and) PEG-100 Stearate, Stearyl Alcohol NF, PEG-55 Propylene Glycol Oleate, Magnesium Aluminum Silicate, Methylparaben NF, Edetate Disodium USP, Butylated Hydroxytoluene, Sodium Thiosulfate USP, Fragrance, Xanthan Gum NF, and Propylparaben NF.

Each cloth of PLEXION^{TS} (sodium sulfacetamide USP 10% and sulfur USP 5%) Cleansing Cloths is coated with a cleanser-based formulation. Each gram of this cleanser-based formulation contains 100 mg of Sodium Sulfacetamide USP and 50 mg of Sulfur USP. The cleanser base consists of: Purified Water USP, Sodium Methyl Oleoyl Taurate, Sodium Cocoyl Isethionate, Disodium Laureth Sulfosuccinate (and) Sodium Lauryl Sulfacetate, Disodium Oleamide MEA Sulfosuccinate, Glycerin USP, Sorbitan Monooleate NF, Glyceryl Stearate (and) PEG-100 Stearate, Stearyl Alcohol NF, Propylene Glycol (and) PEG-55 Propylene Glycol Oleate, Cetyl Alcohol NF, Edetate Disodium USP, Methylparaben NF, PEG-150 Pentaerythrityl Tetrastearate, Butylated Hydroxytoluene NF, Sodium Thiosulfate USP, Aloe Vera Gel Decolorized, Allantoin, Alpha Bisabolol Natural, Fragrance, Propylparaben NF.

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 PLEXION® Cleanser, PLEXION® Cleansing Cloths, PLEXION SCT® or PLEXION TS®. It is also not known whether these PLEXION brand products can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. These PLEXION brand products 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 PLEXION Cleanser, PLEXION Cleansing Cloths, PLEXION SCT or PLEXION TS. 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 these PLEXION brand products 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:

PLEXION® Cleanser: Wash affected areas once or twice daily, 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 cleanser off sooner or using less often.

PLEXION® Cleansing Cloths: Wash affected areas with cleansing cloth once or twice daily, or as directed by your physician. Wet face with water. Wet cloth with a little water and work into a full lather. Cleanse face with cloth for 10–20 seconds avoiding eyes. Rinse thoroughly and pat dry. Throw away cloth. Do not flush.

PLEXION SCT®: Use once daily or as directed by your physician. Wet skin. Apply in a film to entire face, avoiding contact with eyes or mucous membranes. Wait 10 minutes or until dry. Rinse thoroughly with water and pat dry.

PLEXION TS®: Cleanse affected areas. Apply a thin film of PLEXION TS to affected areas 1 to 3 times daily, or as directed by your physician.

HOW SUPPLIED:

PLEXION® (sodium sulfacetamide 10% and sulfur 5%) Cleanser is available in 6 oz. (170.3 g) tube (NDC 99207-741-06) and 12 oz. (340.2 g) bottle (NDC 99207-741-12). **PLEXION® (sodium sulfacetamide 10% and sulfur 5%) Cleansing Cloths** are available in boxes of 30 cloths (3.7 g) (NDC 99207-745-30) and boxes of 60 cloths (3.7 g) (NDC 99207-745-60). **PLEXION SCT® (sodium sulfacetamide 10% and sulfur 5%)** is available in a 4 oz. tube (NDC 99207-744-04). **PLEXION® (sodium sulfacetamide 10% and sulfur 5%) Topical Suspension** is available in 30 g tube (NDC 99207-743-30).

Store at 15°–25°C (59°–77°F).

Manufactured for:

Medics, The Dermatology Company
Scottsdale, AZ 85258

PLEXION® Cleanser, PLEXION TS®, PLEXION SCT® are manufactured by: Contract Pharmaceuticals Limited
Mississauga, Ontario CANADA L5N 6L6
Made in Canada

PLEXION® Cleansing Cloths are manufactured by:
Tapemark
West St. Paul, MN 55118

Prescribing information as of March 2007

PLEXION SCT®: U.S. Pat. 6,514,489; 6,787,160; 6,855,342 & 6,955,825

PLEXION TS®: U.S. Pat. 6,514,489

PLEXION® Cleanser: U.S. Pat. 6,905,675

PLEXION® Cleansing Cloths: U.S. Pat. 6,905,675

& Patents Pending