PLEXION® Cream
(sodium sulfacetamide 9.9%, sulfacetamide 4.8%)
Rx Only
FOR EXTERNAL USE ONLY NOT FOR OPHTHALMIC USE.
DESCRIPTION: Each gram contains 99 mg of sodium sulfacetamide and 48 mg of coloidal sulfur in a vehicle consisting of: water, sodium lauryl sulfate, aluminum silicate, colloidal sulfur, sodium sulfacetamide and 48 mg of colloidal sulfur. The structural formula is:

$Na_2H_2S_2O_4$ + $H_2S_2O_4$ → $Na_2S_2O_4$ + $H_2O$

OVERDOSAGE: In case of oral ingestion, it is readily removed by ordinary laundering without detergent. The product may tend to darken slightly on storage. The product may spread to large, infected, abraded, denuded or severely burned areas. Under these circumstances, any adverse effects produced by the systemic administration of these agents could potentially occur. Therefore, caution and careful supervision should be exercised when prescribing this drug for patients who may be prone to sensitization or who may be sensitive to topical sulfonamides. The use of this product produces signs of hypersensitivity or other untoward reactions, discontinue the use of this product and report the reaction to your physician. If the patient experiences local irritation, systemic lupus erythematosus from topical sodium sulfacetamide have also been reported. In one of these cases, there was a fatal outcome. KEEP OUT OF REACH OF CHILDREN.

STORAGE:
This product is Not for ophtalmic use. Keep bottle tightly closed. The product may spread to large, infected, abraded, denuded or severely burned areas. Under these circumstances, any adverse effects produced by the systemic administration of these agents could potentially occur. Therefore, caution and careful supervision should be exercised when prescribing this drug for patients who may be prone to sensitization or who may be sensitive to topical sulfonamides. The use of this product produces signs of hypersensitivity or other untoward reactions, discontinue the use of this product and report the reaction to your physician. If the patient experiences local irritation, systemic lupus erythematosus from topical sodium sulfacetamide have also been reported. In one of these cases, there was a fatal outcome. KEEP OUT OF REACH OF CHILDREN.

PRECAUTIONS: FOR EXTERNAL USE ONLY.

Nursing Mothers: The drug is excreted in human milk. Because many nursing mothers experience some absorption of sodium sulfacetamide through the skin, the drug should be washed off the skin after use. Because many nursing mothers experience some absorption of sodium sulfacetamide through the skin, it is not known whether the drug is distributed into breast milk. The drug is not known to affect reproduction capacity or cause fetal harm when administered to a pregnant woman. If the mother is known to be sensitive to sodium sulfacetamide, the drug should not be used during pregnancy.

Pediatric Use: Safety and efficacy of sodium sulfacetamide in infants and children under the age of 12 have not been established. The drug is not known to affect reproduction capacity or cause fetal harm when administered to a pregnant woman. If the mother is known to be sensitive to sodium sulfacetamide, the drug should not be used during pregnancy.

Carcinogenesis, Mutagenesis and Impairment of Fertility: Long-term animal studies for carcinogenicity, mutagenesis and impairment of fertility have not been conducted with this product. Although rare, sensitivity to sodium sulfacetamide may occur. Therefore, caution and careful supervision should be exercised when prescribing this drug for patients who may be prone to sensitization or who may be sensitive to topical sulfonamides. The use of this product produces signs of hypersensitivity or other untoward reactions, discontinue the use of this product and report the reaction to your physician. If the patient experiences local irritation, systemic lupus erythematosus from topical sodium sulfacetamide have also been reported. In one of these cases, there was a fatal outcome. KEEP OUT OF REACH OF CHILDREN.

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General: Nonsusceptible organisms, including fungi, may proliferate with the use of this preparation.

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this therapy is to achieve desquamation without irritation, but sodium sulfacetamide and sulfur can cause reddening and scaling of the epidermis. This side effect is unusual in the treatment of acne vulgaris, but patients should be cautioned about the possibility.

Information for Patients: Patients should discontinue the use of this product if the condition becomes worse or if a rash develops in the area being treated or elsewhere. The use of this product should be discontinued and the physician notified if any arthritis, fever or sores in the mouth develop. Avoid contact with eyes, lips and mucous membranes.

Drug Interactions: This product is incompatible with silver preparations.

Carboxenogin, Mutagenesis and Impairment of Fertility: Long-term animal studies for carcinogenic potential have not been performed on this product to date. Studies on reproduction and fertility also have not been performed. Chromosomal nondisjunction has been reported in the yeast, Saccharomyces cerevisiae, following application of sodium sulfacetamide. The significance of this finding to the topical use of sodium sulfacetamide in the human is unknown.

Pregnancy: Category C Animal reproduction studies have not been performed with this product. It is also not known whether this product can affect reproduction capacity or cause fetal harm when administered to a pregnant woman. This product should be used by a pregnant woman only if clearly needed or when potential benefits outweigh potential hazards to the fetus.

Nursing Mothers: It is not known whether this drug is excreted in human milk. However, many drugs are excreted in human milk, caution should be exercised when this product is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children under 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 cases of local hypersensitivity which progressed to a syndrome resembling systemic lupus erythematosus; in one case a fatal outcome was reported (see WARNINGS).

OVERDOSAGE: The oral LD₅₀ of sulfacetamide in mice is 16.5 g/kg. In the event of overdose, emergency treatment should be started immediately.

Manifestations: Overdose may cause nausea and vomiting. Large oral overdose may cause systemic sulfacetamide and sodium sulfacetamide to the precipitation of sulfa crystals in the renal tubules and the urinary tract. For treatment, contact your local Poison Control Center or your doctor.

DOSAGE AND ADMINISTRATION: Cleanse affected areas with light massaging, 1 to 3 times daily or as directed by a physician.

Storage: Store at 20°C to 25°C (68°F to 77°F) excursions permitted between 15°C and 30°C (59°F and 86°F). Sulfacetamide is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when this product is administered to a nursing woman.

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DOSAGE AND ADMINISTRATION: Wash affected areas once or twice daily, or as directed by your physician. Slight discoloration does not impair the efficacy or safety of the product. Keep bottle tightly closed.

HOW SUPPLIED: 10 oz. (285 g) bottles, NDC 57883-402-10

To report a serious adverse event or obtain product information, call 1-855-899-4237.

Distributed by: Arteca Labs
31736 Research Blvd, Suite 125
Austin, TX 78750
1800023 Rev 07/2018

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