AVAR® Cleanser  (sodium sulfacetamide 10%, sulfur 5%)
Rx Only
FOR EXTERNAL USE ONLY NOT FOR OPHTHALMIC USE.

DESCRIPTION: Each gram contains 100 mg of sodium sulfacetamide and 50 mg of colloidal sulfur in a vehicle consisting of: benzyl alcohol, cetyl alcohol, fragrance, glyceryl stearate (and) PEG-100 stearate, magnesium aluminum silicate, phenoxyethanol, propylene glycol, purified water, sodium lauryl sulfate, sodium magnesium alinate, sodium thiosulfate, stearyl alcohol and xanthan gum.

Sodium sulfacetamide is a sulfonamide with antibacterial activity while sulfur acts as a keratolytic agent. Sodium sulfacetamide is {\text{C\subscript{9}H\subscript{7}N\subscript{3}O\subscript{4}S\subscript{2}}} with molecular weight of 254.24. Chemically, sodium sulfacetamide is \( \text{N}-\text{[(4-aminophenyl) sulfonyl]-acetamide} \), monosodium salt, monohydrate. The structural formula is:

\[
\text{H}_2\text{N}\text{SO}_2\text{NCOCH}_3\text{-H}_2\text{O}
\]

Sodium sulfacetamide is an odorless, white, crystalline powder with a bitter taste. It is freely soluble in water, sparingly soluble in alcohol, but practically insoluble in benzene, chloroform and in ether.

CLINICAL PHARMACOLOGY: Sodium sulfacetamide exerts a bacteriostatic effect against sulfonamide sensitive Gram-positive and Gram-negative microorganisms commonly isolated from secondary cutaneous pyogenic infections. It acts by restricting the synthesis of folic acid required by bacteria for growth, by its competition with para-aminobenzoic acid. There is no clinical data available on the degree and rate of systemic absorption of this product when applied to the skin or scalp. However, significant absorption of sodium sulfacetamide through the skin has been reported.

The following in vitro data is available but the clinical significance is unknown. Organisms that show susceptibility to sodium sulfacetamide are: Streptococci, Staphylococci, E. coli, Klebsiella pneumoniae, Pseudomonas pyocyanea, Salmonella species, Proteus vulgaris, Nocardia and Actinomyces.

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 acneis and the formation of free fatty acids.

INDICATIONS: This product is indicated for use in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS: This product is contraindicated in persons with known or suspected hypersensitivity to any of the ingredients of the product. This product is not to be used by patients with kidney disease.

WARNINGS: 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 sodium sulfacetamide have also been reported. In one of these cases, there was a fatal outcome. KEEP OUT OF THE REACH OF CHILDREN.

PRECAUTIONS: FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

General: Non-susceptible organisms, including fungi, may proliferate with the use of this preparation. 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. If the use of this product produces signs of hypersensitivity or other untoward reactions, discontinue use of the preparation. Patients should be carefully observed for possible local irritation or sensitization during long-term therapy. 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. Systemic absorption of topical sulfonamides is greater following application to large, infected, abraded, denuded or severely burned areas. Under these circumstances, any of the adverse effects produced by the systemic administration of these agents could potentially occur, and appropriate observations and laboratory determinations should be performed. 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: 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 also should be discontinued promptly 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.

Carcinogenesis, 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. This is significant to this finding to the topical use of sodium sulfacetamide in the human is unknown.

Pregnancy: Category C. Animal reproduction studies have not been conducted 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. Because 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 opthalmic 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 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 overdosage may cause hematuria, crystalluria and renal shutdown due to the precipitation of sulfas crystals in the renal tubules and the urinary tract. For treatment, contact your local Poison Control Center or your doctor.

DOSAGE AND ADMINISTRATION: Wash affected areas once or twice daily, or as directed by your physician. Wet skin and liberally apply to areas to be cleansed. Massage gently into skin for 10 to 20 seconds, working into a full lather, rinse thoroughly and pat dry. If skin dryness occurs, it may be controlled by rinsing product off sooner or using less frequently.

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). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

NOTICE: Protect from freezing and excessive heat. The product may tend to darken slightly on storage. Slight discoloration does not impair the efficacy or safety of the product. Keep bottle tightly closed.

Occasionally, a slight discoloration of fabric may occur when an excessive amount of the product is used and comes in contact with white fabrics. This discoloration, however, presents no problem, as it is readily removed by ordinary laundering without bleaches.

HOW SUPPLIED: This product is supplied in the following size(s):
8 oz. (227 g) bottles, NDC 0178-0480-08

To report a serious adverse event or obtain product information, call 1-800-260-1087.

Manufactured by:
CO2 Rev 010130
825237
Co2 Rev 010130
Mission Pharmaceutical Company
San Antonio, TX 78230 1355
AVAR® LS Cleanser
(sodium sulfacetamide 10%, sulfur 2%)
Rx Only
FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

DESCRIPTION: Each gram contains 100 mg of sodium sulfacetamide and 20 mg of colloidal sulfur in a vehicle consisting of: benzyl alcohol, cetyl alcohol, fragrance, glycerox stearate and PEG-100 stearate, magnesium aluminum silicate, phenoxethanol, propylene glycol, purified water, sodium lauryl sulfate, sodium magnesium silicate, sodium thiosulfate, stearyl alcohol and xanthan gum.

Sodium sulfacetamide is a sulfonamide with antibacterial activity while sulfur acts as a keratolytic agent. Sodium sulfacetamide is C₆H₄(NH₂)·NaO₃·S·H₂O with molecular weight of 254.24. Chemically, sodium sulfacetamide is N-[4-aminophenyl]sulfonyl]-acetamide, monosodium salt.

The exact mode of action of sulfur in the treatment of acne is unknown, but it has been reported that it inhibits the proliferation of Propionibacterium acnes and the formation of free fatty acids.

INDICATIONS: This product is indicated for use in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS: This product is contraindicated in persons with known or suspected hypersensitivity to any of the ingredients of the product. This product is not to be used by patients with kidney disease.

WARNINGS: 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. In one of these cases, there was a fatal outcome.

KEEP OUT OF THE REACH OF CHILDREN.

PRECAUTIONS: FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

General: Nonsusceptible organisms, including fungi, may proliferate with the use of this preparation. 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. If the use of this product produces signs of hypersensitivity or other untoward reactions, discontinue use of the preparation. Patients should be carefully observed for possible local irritation or sensitization during long-term therapy. 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. Systemic absorption of topical sulfonamides is greater following application to large, infected, abraded, denuded or severely burned areas. Under these circumstances, any of the adverse effects produced by the systemic administration of these agents could potentially occur, and appropriate observations and laboratory determinations should be performed. 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: 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 also should be discontinued promptly 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.

Carcinogenesis, 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.

Pregnancy: Category C. Animal reproduction studies have not been conducted with this product. It is not known whether this product can affect reproductive 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. Because 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 instances of local hypersensitivity which progressed to a syndrome resembling systemic lupus erythematosus, in one case a fatal outcome was reported (see WARNINGS).

OVERDOSE: The oral LD₅₀ of sodium 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 overdosage may cause hematuria, crystalluria and renal shutdown due to the precipitation of sulfas crystals in the renal tubules and the urinary tract. For treatment, contact your local Poison Control Center or your doctor.

DOSAGE AND ADMINISTRATION: Wash affected areas once or twice daily, or as directed by your physician. Wet skin and liberally apply to areas to be cleansed. Massage gently into skin for 10 to 20 seconds, working into a full lather, rinse thoroughly and pat dry. If skin dryness occurs, it may be controlled by rinsing product off sooner or using less frequently.

STORAGE: Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

NOTICE: Protect from freezing and excessive heat. The product may tend to darken slightly on storage. Slight discoloration does not impair the efficacy or safety of the product. Keep bottle tightly closed. Occasionally, a slight discoloration of fabric may occur when an excessive amount of the product is used and comes in contact with white fabrics. This discoloration, however, presents no problem, as it is readily removed by ordinary laundering without bleach.

HOW SUPPLIED: This product is supplied in the following sizes:

- 8 oz. (227 g) bottles, NDC 0178-0475-08

To report a serious adverse event or obtain product information, call 1-800-298-1207.

Manufactured for:

Mission Pharmaceutical Company
San Antonio, TX 78230 1355
sulfacetamide exerts a bacteriostatic effect against sulfonamide sensitive Gram-positive and Gram-negative microorganisms commonly isolated from secondary cutaneous pyogenic infections. This action is achieved by restricting the synthesis of folic acid required by bacteria for growth, by its competition with para-aminobenzoic acid. There is no clinical data available on the degree and rate of systemic absorption of this product when applied to the skin or scalp. However, significant absorption of sodium sulfacetamide through the skin has been reported.

The following in vitro data is available but the clinical significance is unknown. Organisms that show susceptibility to sodium sulfacetamide are: Streptococci, Staphylococci, E. coli, Klebsiella pneumoniae, Pseudomonas pyocyanae, Salmonella species, Proteus vulgaris, Nocardia and Actinomyces.

CONTRAINdications: This product is contraindicated in persons with known or suspected hypersensitivity to any of the ingredients of this product. This product is not to be used by patients with kidney disease.

WARNINGS: 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. In one of these cases, there was a fatal outcome.

PRECAUTIONS: FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

General: Non-susceptible organisms, including fungi, may proliferate with the use of this preparation.

Although rare, sensitivity to sodium sulfacetamide may occur. Therefore, continued medical supervision should be observed when prescribing this drug for patients who may be prone to hypersensitivity to topical sulfonamides. If the use of this product produces signs of hypersensitivity or other untoward reactions, discontinue use of the preparation. Patients should be carefully observed for possible local irritation or sensitization during long-term therapy. 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. Systemic absorption of topical sulfonamides is greatest following application to large, infected, abraded, denuded or severely burned areas. Under these circumstances, any of the adverse effects produced by the systemic administration of these agents could potentially occur, and appropriate observations and laboratory determinations should be performed. 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: 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 also should be discontinued promptly 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.

Carcinogenesis, 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 conducted with this product. It is 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. Because 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 instances 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 hematuria, crystalluria and renal shutdown due to the precipitation of sulf crystals in the renal tubules and the urinary tract. For treatment, contact your local Poison Control Center or your doctor.

DOSAGE AND ADMINISTRATION: Shake well before use. Cleanse affected skin thoroughly and pat dry before each application. Holding can upright, dispense product into palm of hand. Massage the product into the affected area and wait 10 minutes. Rinse thoroughly with water and pat dry. Treat the affected area 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). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized. Contents under pressure. Do not puncture or incinerate.

NOTICE: Protect from freezing and excessive heat. The product may tend to darken slightly on storage. Slight discoloration does not impair the efficacy or safety of the product. Keep dispensing container tightly closed. Occasionally, a slight discoloration of fabric may occur when an excessive amount of the product is used and comes in contact with white fabrics. This discoloration, however, presents no problem, as it is readily removed by ordinary laundering without bleaches.

HOW SUPPLIED: This product is supplied in the following sizes:

3.5 oz. (100 g) can NDC 0176-0658-01

To report a serious adverse event or obtain product information, call 1-800-298-1087.

Manufactured for:

MISSION PHARMACAL COMPANY

1780-West Business Center Drive, Suite 100
San Antonio, TX 782301355

825768

C01 Rev 001150

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.
Sulfacetamide exerts a bacteriostatic effect against sulfonamide-sensitive Gram-positive and Gram-negative microorganisms commonly isolated from secondary cutaneous pyogenic infections. It acts by restricting the synthesis of folic acid required by bacteria for growth, by its competition with para-aminobenzoic acid. There is no clinical significance is unknown. Organisms that show susceptibility to sodium sulfacetamide are: Streptococci, Staphylococci, E. coli, Klebsiella pneumoniae, Pseudomonas poycariaceae, Salmonella species, Proteus vulgaris, Nocardia and Actinomycetes.

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: This product is indicated for use in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS: This product is contraindicated in persons with known or suspected hypersensitivity to any of the ingredients of the product. This product is not to be used by patients with kidney disease.

WARNINGS: 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 have also been reported. In one of these cases, there was a fatal outcome. KEEP OUT OF THE REACH OF CHILDREN.

PRECAUTIONS: FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

CONTRAINDICATIONS: This product is contraindicated in persons with known or suspected hypersensitivity to any of the ingredients of the product. This product is not to be used by patients with kidney disease.

WARNINGS: 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 have also been reported. In one of these cases, there was a fatal outcome. KEEP OUT OF THE REACH OF CHILDREN.

PRECAUTIONS: FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

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

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. If the use of this product produces signs of hypersensitivity or other untoward reactions, discontinue use of the preparation. Patients should be carefully observed for possible local irritation or sensitization during long-term therapy. 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. Systemic absorption of topical sulfonamides is greater following application to large, infected, abraded, denuded or severely burned areas. Under these circumstances, any of the adverse effects produced by the systemic administration of these agents could potentially occur, and appropriate observations and laboratory determinations should be performed. 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: 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 also should be discontinued promptly 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.

Carcinogenesis, 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 conducted 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. Because 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 sulfonamide 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 was reported (see WARNINGS).

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

Manifestations: Overdosage may cause nausea and vomiting. Large oral overdosage may cause hematuria, crystalluria and renal shutdown due to the precipitation of sulfua crystals in the renal tubules and the urinary tract. For treatment, contact your local Poison Control Center or your doctor.

DOSEAGE AND ADMINISTRATION: Shake well before use. Cleanse affected skin thoroughly and pat dry before each application. Holding can upright, dispense product into palm of hand. Massage the product into the affected area and wait 10 minutes. Rinse thoroughly with water and pat dry. Treat the affected area 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). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized. Contents under pressure. Do not puncture or incinerate.

NOTICE: Protect from freezing and excessive heat. The product may tend to darken slightly on storage. Slight discoloration does not impair the efficacy or safety of the product. Keep dispensing container tightly closed.

Occasionally, a slight discoloration of fabric may occur when an excessive amount of the product is used and comes in contact with white fabrics. This discoloration, however, presents no problem, as it is readily removed by ordinary laundering without bleach.

HOW SUPPLIED: This product is supplied in the following sizes:

3.2 oz. (100 g) cans, NDC 0178-0653-01

To report a serious adverse event or obtain product information, call 1-800-286-1087.

Manufactured for: 825770

Aavar LS Foam

Rx Only

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

DESCRIPTION: Each gram contains 100 mg of sodium sulfacetamide and 20 mg of colchicin sulfin in a vehicle consisting al: benzyl alcohol, cetyl alcohol, fragrance, glyceryl stearate (and) FEG-100 stearate, magnesium aluminum silicate, phenoxyethanol, propylene glycol, purified water, sodium lauryl sulfate, sodium magnesium silicate, sodium thiosulfate, stearyl alcohol, and xanthan gum. This product also contains tetrafluorohexane (propellant).

Sodium sulfacetamide is a sulfonamide with antibacterial activity while sulfur acts as a keratolytic agent. Sodium sulfacetamide is C₈H₇N₄NaO₃S·H₂O with molecular weight of 254.24. Chemically, sodium sulfacetamide is N-[4-amino-phenyl]-sulfonyl-acetamide, monosodium salt, monohydrate. The structural formula is:

\[
\text{H}_2\text{N SO}_2\text{NCOCH}_3·\text{H}_2\text{O}
\]

Sodium sulfacetamide is an odorless, white, crystalline powder with a bitter taste. It is freely soluble in water, sparingly soluble in alcohol, while practically insoluble in benzene, in chloroform and in ether.

CLINICAL PHARMACOLOGY: Sodium sulfacetamide exerts a bacteriostatic effect against sulfonamide-sensitive Gram-positive and Gram-negative microorganisms commonly isolated from secondary cutaneous pyogenic infections. It acts by restricting the synthesis of folic acid required by bacteria for growth, by its competition with para-aminobenzoic acid. There is no clinical data available on the degree and rate of systemic absorption of this product when applied to the skin or scalp. However, significant absorption of sodium sulfacetamide through the skin has been reported.

The following in vitro data is available but the clinical significance is unknown. Organisms that show susceptibility to sodium sulfacetamide are: Streptococci, Staphylococci, E. coli, Klebsiella pneumoniae, Pseudomonas poycariaceae, Salmonella species, Proteus vulgaris, Nocardia and Actinomycetes.
AVAR-e Emollient Cream (sodium sulfacetamide 10%, sulfur 5%) Rx Only
FOR EXTERNAL USE ONLY NOT FOR OPHTHALMIC USE.

DESCRIPTION: Each gram contains 100 mg of sodium sulfacetamide and 50 mg of colloidal sulfur in a vehicle consisting of: benzyl alcohol, cetyl alcohol, disodium EDTA, fragrance, glyceryl stearate (and) PEG-100 stearate, magnesium aluminum silicate, PEG-150 dioleate, phenoxethanol, polyethylene glycol 400, purified water, sodium lauryl sulfate, sodium thiophosphate, stearyl alcohol and xanthan gum.

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

\[
\text{H}_2\text{N} + \text{SO}_2\text{NCOCH}_3 \cdot \text{H}_2\text{O}
\]

Sodium sulfacetamide is an odorless, white, crystalline powder with a bitter taste. It is freely soluble in water, sparingly soluble in alcohol, while practically insoluble in benzene, in chloroform and in ether.

CLINICAL PHARMACOLOGY: Sodium sulfacetamide exerts a bacteriostatic effect against sulfonamide sensitive Gram-positive and Gram-negative microorganisms commonly isolated from secondary cutaneous pyogenic infections. It acts by restricting the synthesis of folic acid required by bacteria for growth, by its competition with para-aminobenzoic acid. There is no clinical data available on the degree and rate of systemic absorption of this product when applied to the skin or scalp. However, significant absorption of sodium sulfacetamide through the skin has been reported.

The following intra data is available but the clinical significance is unknown. Organisms that show susceptibility to sodium sulfacetamide are: Streptococci, Staphylococci, E. coli, Klebsiella pneumoniae, Pseudomonas pyocyanea, Salmonella species, Proteus vulgaris, Nocardia and Actinomyces.

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 acne and the formation of free fatty acids.

INDICATIONS: This product is indicated for use in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS: This product is contraindicated in persons with known or suspected hypersensitivity to any of the ingredients of the product. This product is not to be used by patients with kidney disease.

WARNINGS: 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. In one of these cases, there was a fatal outcome.

KEEP OUT OF THE REACH OF CHILDREN.

PRECAUTIONS: FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

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

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. If the use of this product produces signs of hypersensitivity or other untoward reactions, discontinue use of the preparation. Patients should be carefully observed for possible local irritation or sensitization during long-term therapy. 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. Systemic absorption of topical sulfonamides is greater following application to large, infected, abraded, denuded or severely burned areas. Under these circumstances, any of the adverse effects produced by the systemic administration of these agents could potentially occur, and appropriate observations and laboratory determinations should be performed.

The object of this therapy is to achieve desquamation without irritation, but both 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: 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 also should be discontinued promptly if 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.

Carcinogenesis, 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 conducted 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. Because 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 instances 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 mg/kg. In the event of overdosage, emergency treatment should be started immediately.

Manifestations: Overdosage may cause nausea and vomiting. Large oral overdosage may cause hematuria, crystalluria and renal shutdown due to the precipitation of sulfua 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. Apply a thin layer to the 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 (between 59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

NOTICE: Protect from freezing and excessive heat. The product may tend to darken slightly on storage. Slight discoloration does not impair the efficacy or safety of the product. Keep bottle tightly closed.

HOW SUPPLIED: This product is supplied in the following size(s):
2 oz. (57 g) bottles. NDC 0784-0470-02

To report a serious adverse event or obtain product information, call 1-800-298-1087.

825234
C02 Rev 010130

Manufactured for:
MISSION PHARMACEUTICAL COMPANY
San Antonio, TX 78230-1355
AVAR-<sup>e</sup> LS Emollient Cream
(sodium sulfacetamide 10%, sulfur 2%)
Rx Only
FOR EXTERNAL USE ONLY NOT FOR OPHTHALMIC USE.

DESCRIPTION: Each gram contains 100 mg of sodium sulfacetamide and 20 mg of colloidal sulfur in a vehicle consisting of: benzyl alcohol, cetyl alcohol, diisooctyl adipate, fragrance, glyceryl stearate (and) PEG-100 stearate, magnesium aluminum silicate, PEG-150 distearate, phenoxethanol, polyethylene glycol 400, purified water, sodium lauryl sulfate, sodium thiosulfate, stearyl alcohol and xanthan gum.

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

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H2N
\[\text{SO}_{2}\text{NCOCH}_3\text{Na} \cdot H_2O\]
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Sodium sulfacetamide is an odorless, white, crystalline powder with a bitter taste. It is freely soluble in water, sparingly soluble in alcohol, and practically insoluble in benzene, in chloroform and in ether.

CLINICAL PHARMACOLOGY: Sodium sulfacetamide exerts a bacteriostatic effect against sulfonamide-sensitive Gram-positive and Gram-negative microorganisms commonly isolated from secondary cutaneous pyogenic infections. It acts by restricting the synthesis of folic acid required by bacteria for growth, by its competition with para-aminobenzoic acid. There is no clinical data available on the degree and rate of systemic absorption of this product when applied to the skin or scalp. However, significant absorption of sodium sulfacetamide through the skin has been reported.

The following in vitro data is available but the clinical significance is unknown. Organisms that show susceptibility to sodium sulfacetamide are: Streptococci, Staphylococci, E. coli, Klebsiella pneumoniae, Pseudomonas pyocyanea, Salmonella species, Proteus vulgaris, Nocardia and Actinomyces.

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 acne and the formation of free fatty acids.

INDICATIONS: This product is indicated for use in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS: This product is contraindicated in persons with known or suspected hypersensitivity to any of the ingredients of the product. This product is not to be used by patients with kidney disease.

WARNINGS: 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. In one of these cases, there was a fatal outcome. KEEP OUT OF THE REACH OF CHILDREN.

PRECAUTIONS: FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

General: Nonsusceptible organisms, including fungi, may proliferate with the use of this preparation. 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. If the use of this product produces signs of hypersensitivity or other untoward reactions, discontinue use of the product. Patients should be carefully observed for possible local irritation or sensitization during long-term therapy. 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. Systemic absorption of topical sulfonamides is greater following application to large, infected, abraded, denuded or severely burned areas. Under these circumstances, any of the adverse effects produced by the systemic administration of these agents could potentially occur, and appropriate observations and laboratory determinations should be performed.

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: 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 also should be discontinued promptly 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.

Carcinogenesis, 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 conducted 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. Because 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 have been 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 was reported (see WARNINGS).

OVERDOSAGE: The oral LD<sub>50</sub> 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 overdosage may cause hematuria, crystalluria and renal shutdown due 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. Apply a thin layer to the affected areas with light massage, 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 (between 59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

NOTICE: Protect from freezing and excessive heat. The product may tend to darken slightly on storage. Slight discoloration does not impair the efficacy or safety of the product. Keep bottle tightly closed.

 Occasionally, a slight discoloration of fabric may occur when an excessive amount of the product is used and comes in contact with white fabrics. This discoloration, however, presents no problem, as it is readily removed by ordinary laundering without bleaches.

HOW SUPPLIED: This product is supplied in the following sizes:
2 oz. (57 g) bottles, NOC 0178-0465-02
To report a serious adverse event or obtain product information, call 1-800-296-1087.

825210
C02 Rev 010130
Manufactured for:
MISSION PHARMACEUTICAL COMPANY
San Antonio, TX 78230 1355
**AVAR-e Green® Cream** (sodium sulfacetamide 10%, sulfate 5%)  
Rx Only  
FOR EXTERNAL USE ONLY NOT FOR OPHTHALMIC USE.

**DESCRIPTION:** Each gram contains 100 mg of sodium sulfacetamide and 50 mg of colloidal sulfur in a vehicle consisting of: benzyl alcohol, cetyl alcohol, chromium oxide green, disodium EDTA, fragrance, glyceryl stearate (and) PEG-100 stearate, magnesium aluminum silicate, PEG-150 distearate, p-phenylbenzimidazole, polyethylene glycol 400, purified water, sodium lauryl sulfate, sodium thiosulfate, stearyl alcohol and xanthan gum.

Sodium sulfacetamide is a sulfonamide with antibacterial activity while sulfur acts as a keratolytic agent. Sodium sulfacetamide is CaH9N2NaOaS·H2O with molecular weight of 254.24. Chemically, sodium sulfacetamide is N-[4-aminoethyl]-sodium sulfonamide, monosodium salt, monohydrate. The structural formula is:

\[
\text{H} \quad \text{N} \quad \text{SO}_2\text{NaCOOH} \quad \text{H}_2\text{O}
\]

Sodium sulfacetamide is an odorless, white, crystalline powder with a bitter taste. It is freely soluble in water, solutions of alcohol, while practically insoluble in benzene, in chloroform and in ether.

**CLINICAL PHARMACOLOGY:** The most widely accepted mechanism of action of sulfonamides is the Woods-Ploite theory, which is based on the fact that sulfonamides act as competitive antagonists to para-aminobenzoic acid (PABA), an essential component of 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 usually 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 Propionibacema acne and the formation of free fatty acids.

**INDICATIONS:** This product is indicated for use in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

**CONTRAINDICATIONS:** This product is contraindicated in persons who have demonstrated hypersensitivity to any of the ingredients of the product. This product is not to be used by patients with kidney disease.

**WARNINGS:** Sulfonamides are known to cause Stevens-Johnson syndrome in hypersensitive individuals. Stevens-Johnson syndrome has also been reported following the use of sodium sulfacetamide topically. Cases of drug-induced systemic lupus erythematosus from topical sulfacetamide also have been reported. In one of these cases, there was a fatal outcome.

**KEEP OUT OF THE REACH OF CHILDREN.**

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

**General:** Non-susceptible organisms, including fungi, may proliferate with the use of this preparation.

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. If the use of this product produces signs of hypersensitivity or other untoward reactions, this drug should be discontinued promptly 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.

**Pharmacology:** Sodium sulfacetamide exerts a bacteriostatic effect against sulfonamide sensitive Gram-positive and Gram-negative microorganisms commonly isolated from secondary cutaneous pyogenic infections.

**Carcinogenesis, 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 conducted with this product. It is also not known whether this product should be used by a pregnant woman when this product is administered to a nursing woman.

**Nursing Mothers:** It is not known whether this drug 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.

**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 instances 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 overdosage, emergency treatment should be started immediately.

**Manifestations:** Overdosage may cause nausea and vomiting. Large oral overdosage may cause hematuria, crystalluria and renal shutdown due 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. Apply a thin layer to the 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). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

**NOTICE:** Protect from freezing and excessive heat. The product may tend to darken slightly on storage. Slight discoloration does not impair the efficacy or safety of the product. Keep bottle tightly closed.

Occasionally, a slight discoloration of fabric may occur when an excessive amount of the product is used and comes in contact with white fabrics. This discoloration, however, presents no problem, as it is readily removed by ordinary laundering without bleaches.

**HOW SUPPLIED:** This product is supplied in the following sizes:
- 2 oz. (57 g) bottles, NDC 0178-0460-02
To report a serious adverse event or obtain product information, call 1-800-298-1087.

R25216  
C02 Rev 010130

Manufactured for: MISSION PHARMACAL COMPANY  
San Antonio, TX 78230 1355