**OVACE- sulfacetamide sodium liquid**
**Mission Pharmacal Company**

*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.*

---

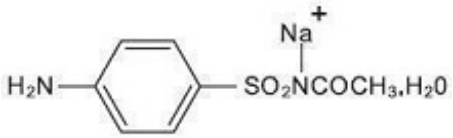
**OVACE® Wash (sodium sulfacetamide 10%)**

**Rx Only**

## DESCRIPTION:

Each gram contains 100 mg of sodium sulfacetamide in a vehicle consisting of: cocamidopropyl betaine, disodium EDTA, methylparaben, PEG-60 almond triglycerides, PEG-150 pentaerythrityl tetrastearate (and) aqua (and) PEG-6 caprylic/capric glycerides, purified water, sodium laureth sulfate and sodium thiosulfate.

Sodium sulfacetamide is a sulfonamide with antibacterial activity. Sodium sulfacetamide is $C_8H_9N_2NaO_3S{\cdot}H_2O$ with molecular weight of 254.24. Chemically, sodium sulfacetamide is N-[(4-aminophenyl) sulfonyl]-acetamide, monosodium salt, monohydrate. The structural formula is:




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 pyocyanea, Salmonella species, Proteus vulgaris, Nocardia and Actinomyces.

## INDICATIONS AND USAGE:

This product is intended for topical application in the following scaling dermatoses: seborrheic dermatitis and seborrhea sicca (dandruff). It also is indicated for the treatment of secondary bacterial infections of the skin due to organisms susceptible to sulfonamides.

## 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.

**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, 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 $LD_{50}$ 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:

*Seborrheic dermatitis including seborrhea sicca* - Wash affected areas twice daily (morning and evening) 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 working into a full lather, rinse thoroughly, pat dry and repeat after 10 to 20 seconds. Rinsing with plain water will remove any excess medication. Repeat application as described above for 8 to 10 days or as directed by your physician. lf skin dryness occurs it may be controlled by rinsing cleanser off sooner or using less frequently. Regular shampooing following the use of this product is not necessary, but the hair should be shampooed at least once a week. As the condition subsides, the interval between applications may be lengthened. Applications once or twice weekly or every other week may prevent recurrence. Should the condition recur after stopping therapy, the application of this product should be reinitiated as at the beginning of treatment.

*Secondary cutaneous bacterial infections* - Wash affected areas twice daily (morning and evening) 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 to 20 seconds working into a full lather, rinse thoroughly and pat dry. Rinsing with plain water will remove any excess medication. Repeat application as described above for 8 to 10 days or as directed by your physician. If skin dryness occurs it may be controlled by rinsing cleanser 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 bleaches.

## HOW SUPPLIED:

This product is supplied in the following size(s):
6 fl. oz. (180 mL) bottles, **NDC** 0178-0499-06
12 fl. oz. (355 mL) bottles, **NDC** 0178-0499-12
16 fl. oz. (480 mL) bottles, **NDC** 0178-0499-16

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

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

**DESCRIPTION:** Each gram of OVACE® Wash (sodium sulfacetamide 10% w/w) contains 100 mg of sodium sulfacetamide in a vehicle consisting of cocamidopropyl betaine, disodium EDTA, methylparaben, PEG-60 almond triglycerides, PEG-150 pentaerythrityl tetrastearate (and) aqua (and) PEG-6 caprylic/capric glycerides, purified water, sodium laureth sulfate and sodium thiosulfate.

**INDICATIONS AND USAGE:** OVACE® Wash is intended for topical application in the following scaling dermatoses: seborrheic dermatitis and seborrhea sicca (dandruff). It also is indicated for the treatment of secondary bacterial infections of the skin due to organisms susceptible to sulfonamides. See patient information for full prescribing details.

**DOSAGE AND ADMINISTRATION:**
*Seborrheic dermatitis including seborrhea sicca* - Wash affected areas twice daily (morning and evening), 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 working into a full lather, rinse thoroughly, pat dry and repeat after 10 to 20 seconds. Rinsing with plain water will remove any excess medication. Repeat application as described for 8 to 10 days. If skin dryness occurs it may be controlled by rinsing cleanser off sooner or using less frequently. Regular shampooing following OVACE® Wash is not necessary, but the hair should be shampooed at least once a week. As the condition subsides, the interval between applications may be lengthened. Applications once or twice weekly or every other week may prevent recurrence. Should the condition recur after stopping therapy, the application of OVACE® Wash should be reinitiated as at the beginning of treatment.

*Secondary cutaneous bacterial infections* - 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. Rinsing with plain water will remove any excess medication. Repeat application as described for 8 to 10 days. If skin dryness occurs it may be controlled by rinsing cleanser off sooner or using less often.

**WARNING: FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.**
**KEEP OUT OF REACH OF CHILDREN.** Keep container tightly closed.

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F).
See USP Controlled Room Temperature. Protect from freezing and excessive heat.

Distributed by:
Mission Pharmacal Company
San Antonio, TX 78230-1355

Patent Pending

N 3 01780 49912 2

℞ ONLY

NDC 0178-0499-12

# OVACE®

## {SODIUM SULFACETAMIDE 10%}

## WASH

12 fl. oz. (355 mL)

**DESCRIPTION:** Each gram of OVACE® Wash (sodium sulfacetamide 10% w/w) contains 100 mg of sodium sulfacetamide in a vehicle consisting of: cocamidopropyl betaine, disodium EDTA, methylparaben, PEG-60 almond triglycerides, PEG-150 pentaerythrityl tetrastearate (and) aqua (and) PEG-6 caprylic/capric glycerides, purified water, sodium laureth sulfate and sodium thiosulfate.

**INDICATIONS AND USAGE:** OVACE® Wash is intended for topical application in the following scaling dermatoses: seborrheic dermatitis and seborrhea sicca (dandruff). It also is indicated for the treatment of secondary bacterial infections of the skin due to organisms susceptible to sulfonamides. See patient information for full prescribing details.

**DOSAGE AND ADMINISTRATION:** *Seborrheic dermatitis including seborrhea sicca* - Wash affected areas twice daily (morning and evening) 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 working into a full lather, rinse thoroughly, pat dry and repeat after 10 to 20 seconds. Rinsing with plain water will remove any excess medication. Repeat application as described above for 8 to 10 days or as directed by your physician. If skin dryness occurs it may be controlled by rinsing cleanser off sooner or using less frequently. Regular shampooing following OVACE® Wash is not necessary, but the hair should be shampooed at least once a week. As the condition subsides, the interval between applications may be lengthened. Applications once or twice weekly or every other week may prevent recurrence. Should the condition recur after stopping therapy, the application of OVACE® Wash should be reinitiated as at the beginning of treatment.

*Secondary cutaneous bacterial infections* - Wash affected areas twice daily (morning and evening) 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 to 20 seconds working into a full lather, rinse thoroughly and pat dry. Rinsing with plain water will remove any excess medication. Repeat application as described above for 8 to 10 days or as directed by your physician. If skin dryness occurs it may be controlled by rinsing cleanser off sooner or using less frequently.

**WARNING: FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.**
**KEEP OUT OF REACH OF CHILDREN.** Keep container tightly closed.

Store at 20°C - 25°C (68°F - 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). See USP Controlled Room Temperature. Protect from freezing and excessive heat. Lot number and expiration date on bottom of bottle.

Manufactured for:
MISSION PHARMACAL COMPANY
San Antonio, TX 78230 1355
C01 Rev 001130

N 3 01780 49906 1

℞ ONLY

**NDC** 0178-0499-06

# OVACE®

## (SODIUM SULFACETAMIDE 10%) WASH

**6 fl. oz. (180 mL)**

Mission® PHARMACAL

NDC 0178-0499-16

Rx Only

# OVACE®

(sodium sulfacetamide 10%)

# WASH

16 fl. oz. (480 mL)

**DESCRIPTION:** Each gram contains 100 mg of sodium sulfacetamide in a vehicle consisting of: cocamidopropyl betaine, disodium EDTA, methylparaben, PEG-60 almond triglycerides, PEG-150 pentaerythrityl tetrastearate (and) aqua (and) PEG-6 caprylic/capric glycerides, purified water, sodium laureth sulfate and sodium thiosulfate.

**INDICATIONS:** This product is intended for topical application in the following scaling dermatoses: seborrheic dermatitis and seborrhea sicca (dandruff). It also is indicated for the treatment of secondary bacterial infections of the skin due to organisms susceptible to sulfonamides.

**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.

**DOSAGE AND ADMINISTRATION:** *Seborrheic dermatitis including seborrhea sicca* - Wash affected areas twice daily (morning and evening) 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 working into a full lather, rinse thoroughly, pat dry and repeat after 10 to 20 seconds. Rinsing with plain water will remove any excess medication. Repeat application as described above for 8 to 10 days or as directed by your physician. If skin dryness occurs it may be controlled by rinsing cleanser off sooner or using less frequently. Regular shampooing following the use of this product is not necessary, but the hair should be shampooed at least once a week. As the condition subsides, the interval between applications may be lengthened. Applications once or twice weekly or every other week may prevent recurrence. Should the condition recur after stopping therapy, the application of this product should be reinitiated as at the beginning of treatment.

*Secondary cutaneous bacterial infections* - Wash affected areas twice daily (morning and evening) 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 to 20 seconds working into a full lather, rinse thoroughly and pat dry. Rinsing with plain water will remove any excess medication. Repeat application as described above for 8 to 10 days or as directed by your physician. If skin dryness occurs it may be controlled by rinsing cleanser off sooner or using less frequently.

See package insert for full prescribing information.

**WARNING: FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.**
**KEEP OUT OF REACH OF CHILDREN.** Avoid contact with eyes, lips and mucous membranes.

**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). Protect from freezing and excessive heat. Keep bottle tightly closed. Lot number and expiration date on bottom of bottle.

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

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

L0499-16.01 C01 Rev 011130

Mission® PHARMACAL

N 3 01780 49916 0

## OVACE

sulfacetamide sodium liquid

### Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:0178-0499 |
| **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 mL |

### Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **COCAMIDOPROPYL BETAINE** (UNII: 5OCF3O11KX) | |
| **EDETATE DISODIUM** (UNII: 7FLD91C86K) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |

| | |
|---|---|
| **PEG-60 ALMOND GLYCERIDES** (UNII: 4Y0E651N0F) | |
| **PEG-150 PENTAERYTHRITYL TETRASTEARATE** (UNII: 8L4OOQ76AM) | |
| **PEG-6 CAPRYLIC/CAPRIC GLYCERIDES** (UNII: GO50W2HWO8) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SODIUM LAURETH SULFATE** (UNII: BPV390UAP0) | |
| **SODIUM THIOSULFATE** (UNII: HX1032V43M) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | yellow (light yellow) | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | | **Imprint Code** | |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0178-0499-12 | 355 mL in 1 BOTTLE, PLASTIC | | |
| **2** | NDC:0178-0499-06 | 180 mL in 1 BOTTLE, PLASTIC | | |
| **3** | NDC:0178-0499-16 | 480 mL in 1 BOTTLE, PLASTIC | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 09/15/2011 | |

## Labeler - Mission Pharmacal Company (008117095)

Revised: 1/2014 Mission Pharmacal Company