

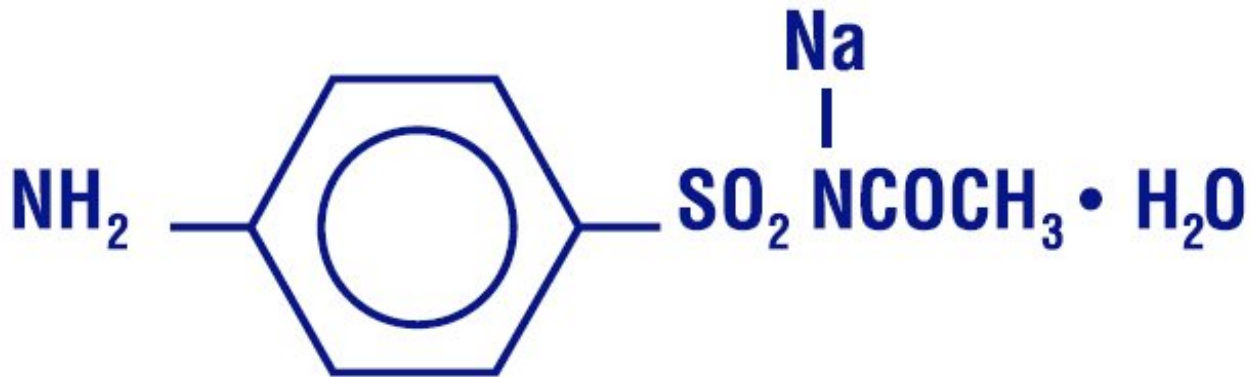
KLARON- sulfacetamide sodium lotion
Bausch Health US, LLC

Klaron[®]
sodium sulfacetamide lotion
Lotion, 10 %

DESCRIPTION

Each mL of Klaron[®] (sodium sulfacetamide lotion) Lotion, 10% contains 100 mg of sodium sulfacetamide in a vehicle consisting of edetic acid, hydroxyethyl cellulose, lauramide DEA, methylparaben, PEG-400 monolaurate, propylene glycol, purified water, silicone emulsion, sodium chloride, sodium metabisulfite, and xanthan gum.

Sodium sulfacetamide is a sulfonamide with antibacterial activity. Chemically, sodium sulfacetamide is N' -[(4-amino phenyl) sulfonyl] - acetamide, monosodium salt, monohydrate. The structural formula is:



CLINICAL PHARMACOLOGY

The most widely accepted mechanism of action of sulfonamides is the Woods-Fildes theory, based on sulfonamides acting as a competitive inhibitor of para-aminobenzoic acid (PABA) utilization, an essential component for bacterial growth. While absorption through intact skin in humans has not been determined, in vitro studies with human cadaver skin indicated a percutaneous absorption of about 4%. Sodium sulfacetamide is readily absorbed from the gastrointestinal tract when taken orally and excreted in the urine largely unchanged. The biological half-life has been reported to be between 7 to 13 hours.

The pharmacokinetics of sulfacetamide and its major metabolite sulfanilamide in Klaron Lotion was evaluated in adult subjects (N=14) with *acne vulgaris*. The subjects applied Klaron Lotion to their face, back, chest, and shoulders every 12 hours for 28 days. The percentage of the applied dose of Klaron Lotion excreted in the urine as sulfacetamide plus sulfanilamide ranged from 0.08 to 0.33%.

INDICATIONS

Klaron Lotion is indicated in the topical treatment of *acne vulgaris*.

CONTRAINDICATIONS

Klaron Lotion is contraindicated for use by patients having known hypersensitivity to sulfonamides or any other component of this preparation (see **WARNINGS**).

WARNINGS

Fatalities have occurred, although rarely, due to severe reactions to sulfonamides including Stevens-Johnson syndrome, toxic epidermal necrolysis, fulminant hepatic necrosis, agranulocytosis, aplastic anemia, and other blood dyscrasias. Hypersensitivity reactions may occur when a sulfonamide is readministered, irrespective of the route of administration. Sensitivity reactions have been reported in individuals with no prior history of sulfonamide hypersensitivity. At the first sign of hypersensitivity, skin rash, or other reactions, discontinue use of this preparation (see **ADVERSE REACTIONS**).

Klaron Lotion contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people (see **CONTRAINDICATIONS**).

PRECAUTIONS

General

For external use only. Keep away from eyes. 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. Hypersensitivity reactions may occur when a sulfonamide is readministered irrespective of the route of administration, and cross-sensitivity between different sulfonamides may occur. Sodium sulfacetamide can cause reddening and scaling of the skin. Particular caution should be employed if areas of involved skin to be treated are denuded or abraded.

Keep out of reach of children.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been performed to evaluate carcinogenic potential.

Animal reproduction studies have not been conducted with Klaron Lotion. It is also not known whether Klaron Lotion can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Klaron Lotion should be given to a pregnant woman only if clearly needed.

Kernicterus may occur in the newborn as a result of treatment of a pregnant woman at term with orally administered sulfonamide. There are no adequate and well-controlled studies of Klaron Lotion in pregnant women, and it is not known whether topically applied sulfonamides can cause fetal harm when administered to a pregnant woman.

Nursing Mothers

It is not known whether sodium sulfacetamide is excreted in human milk following topical use of Klaron Lotion. Systemically administered sulfonamides are capable of producing kernicterus in the infants of lactating women. Small amounts of orally administered sulfonamides have been reported to be eliminated in human milk. Because many drugs are excreted in human milk, caution should be exercised in prescribing for nursing women.

Pediatric Use

Safety and effectiveness in pediatric patients under the age of 12 have not been established.

ADVERSE REACTIONS

In controlled clinical trials for the management of *acne vulgaris*, the occurrence of adverse reactions associated with the use of Klaron Lotion was infrequent and restricted to local events. The total incidence of adverse reactions reported in these studies was less than 2%. Only one of 105 patients treated with Klaron Lotion had adverse reactions of erythema, itching, and edema. It has been reported that sodium sulfacetamide may cause local irritation, stinging, and burning. While the irritation may be transient, occasionally the use of medication has to be discontinued.

To report SUSPECTED ADVERSE REACTIONS, contact Bausch Health US, LLC at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION

Apply a thin film to affected areas twice daily.

HOW SUPPLIED

4 fl oz (118 mL) Bottles NDC 0187-5198-04

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Shake well before using. Keep tightly closed.

Distributed by:

Bausch Health US, LLC
Bridgewater, NJ 08807 USA

Manufactured by:

Bausch Health Companies Inc.
Laval, Quebec H7L 4A8, Canada

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PRINCIPAL DISPLAY PANEL - 118 mL Bottle Carton

NDC 0187-5198-04

Rx only

Klaron[®]
sodium
sulfacetamide
lotion

Lotion, 10%

FOR TOPICAL USE ONLY
SHAKE WELL BEFORE USING

One 4 fl oz (118 mL) Bottle

Ortho Dermatologics



KLARON

sulfacetamide sodium lotion

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0187-5198
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
EDETIC ACID (UNII: 9G34HU7RV0)				
HYDROXYETHYL CELLULOSE (2000 MPAS AT 1%) (UNII: S38J6RZN16)				
LAURIC DIETHANOLAMIDE (UNII: I29I2VHG38)				
methylparaben (UNII: A2I8C7HI9T)				
water (UNII: 059QF0KO0R)				
sodium chloride (UNII: 451W47IQ8X)				
sodium metabisulfite (UNII: 4VON5FNS3C)				
xanthan gum (UNII: TTV12P4NEE)				
PEG-8 LAURATE (UNII: 762O8IWA10)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0187-5198-04	1 in 1 CARTON	12/23/1996	
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA		NDA019931	12/23/1996	

Labeler - Bausch Health US, LLC (831922468)

Establishment			
Name	Address	ID/FEI	Business Operations
Bausch Health Companies Inc		245141858	MANUFACTURE(0187-5198) , PACK(0187-5198) , LABEL(0187-5198)

Revised: 8/2020

Bausch Health US, LLC