

BIOCORNEUM ADVANCED SCAR TREATMENT ANTI-ITCH- hydrocortisone acetate

1% gel

Sientra, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredient

Active Ingredient Purpose

Hydrocortisone acetate 1%.....Anti-itch

Uses

For the temporary relief of itching associated with minor skin irritations, inflammation and rashes due to eczema, insect bites, soaps, detergents and cosmetics. Other uses of this product should be only under the advice and supervision of a physician.

Biocorneum can reduce the appearance of scars and is ideal for use on any intact skin surface, including skin that flexes,(such as joints).

Directions

Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily for up to 7 days. Children under 2 years of age: Do not use, consult a physician.

Other Information

Protect product in this container from excessive heat and direct sun.

Inactive Ingredients

Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethyl Isosorbide, Pentylene Glycol, Propylene Glycol, Silicon Dioxide

Questions?

Call 888.708.0808

Keep out of reach of children. If swallowed, get medical help or contact a poison control center immediately.

For external use only.

Avoid contact with eyes.

Do not use for treatment of diaper rash.

Stop use and ask a doctor if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

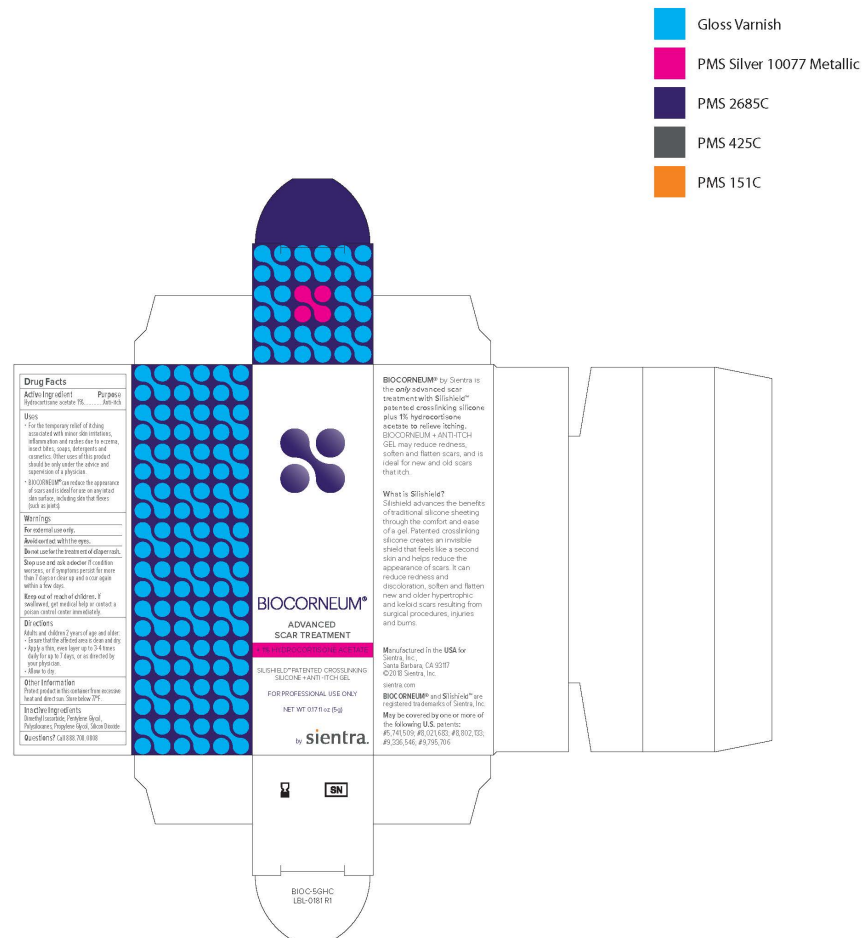
Keep out of the reach of children.

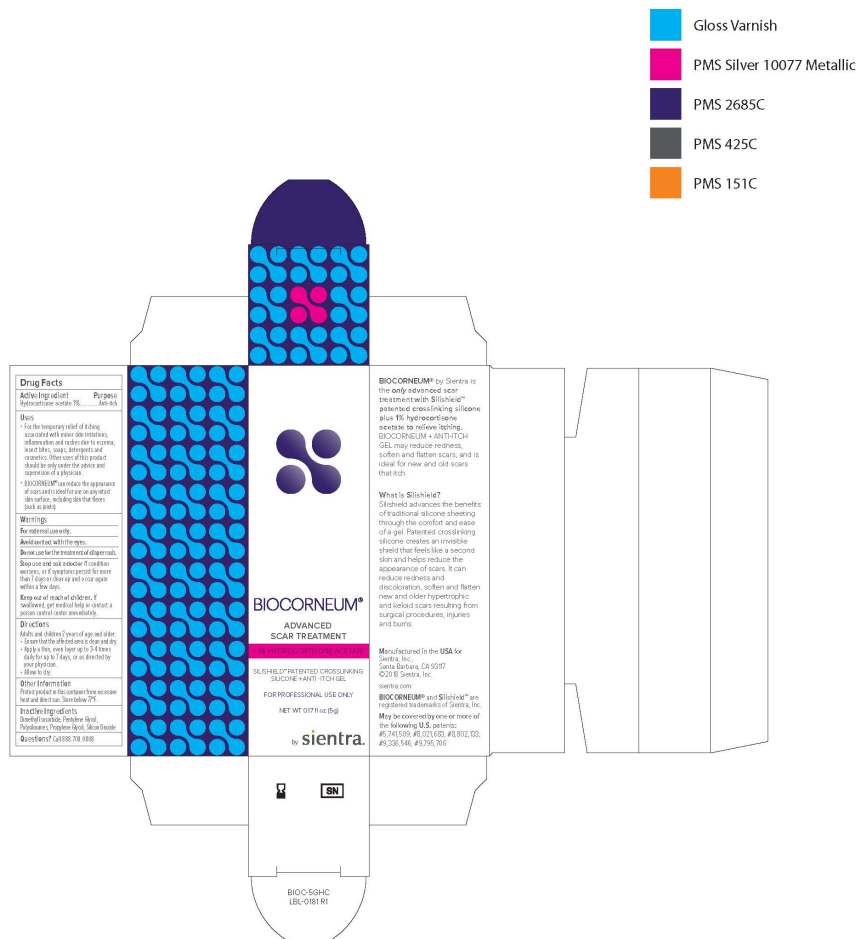
If swallowed, get medical help or contact a poison control center immediately.

Directions

Adults and children 2 years of age and older:

- Ensure that the affected area is clean and dry.
- Apply a thin, even layer up to 3-4 times daily for up to 7 days, or as directed by your physician.
- Allow to dry.





BIOCORNEUM ADVANCED SCAR TREATMENT ANTI-ITCH

hydrocortisone acetate 1% gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71241-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE ACETATE (UNII: 3X7931P074) (HYDROCORTISONE - UNII:W14X0 X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE CROSSPOLYMER (450000 MPAS AT 12 % IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	1 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71241-002-99	1 in 1 CARTON	05/08/2018	
1	NDC:71241-002-05	5 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/08/2018	

Labeler - Sientra, Inc. (010209877)

Revised: 1/2021

Sientra, Inc.