

EBBE- colloidal oatmeal gel
BLUE SEA LABORATORIES SL.

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.

AD1 ECZEMA GEL
EBBE SEAWATER ESSENTIALS

Drug Facts

Active ingredients

Colloidal Oatmeal 2%

Purpose

Skin protectant

Uses

Temporarily protects and helps relieve minor skin irritation and itching due to: ■ Eczema ■ Rashes

Warnings

For external use only.

When using this product

■ do not get into the eyes.

Stop use and ask a doctor if

■ condition worsens.

■ symptoms last more than 7 days or clear up and occur again within a few days.

Keep out of reach of children.

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

Directions

Apply as needed.

Inactive ingredients

acetyl hexapeptide-49, aloe barbadensis (aloe vera) leaf juice, caprylhydroxamic acid, caprylyl glycol, disodium succinoyl glycyrrhetinate, glycerin, hyaluronic acid, seawater, sodium hydroxide, tetrasodium EDTA, xanthan gum

Other information

For use on mild to moderate eczema or as directed by a physician. Store at room temperature. You may

report serious side effects to the phone number provided under Questions? below.

Questions? Call
844-EBBE-866

INSTRUCTIONS FOR USE: Apply to the affected area twice daily (or as needed) and massage gently.
Store in cool, dry place

AD¹ ATOPIC DERMATITIS GEL

Atopic dermatitis is a skin alteration that consists of dry, flaky and irritated skin.

EBBE atopic dermatitis gel (AD1) hydrates and provides the emollience required to balance and restore the cutaneous barrier function.

The high molecular weight **hyaluronic acid** forms a protective film over the skin's surface layers, thereby reducing the loss of transepidermal water and providing intense and prolonged hydration.

The formula contains ultra-purified **seawater** with more than 75 minerals and trace elements.

EBBE atopic dermatitis gel (AD1) reduces itching and flaking, whilst improving the skin's hydration and elasticity.

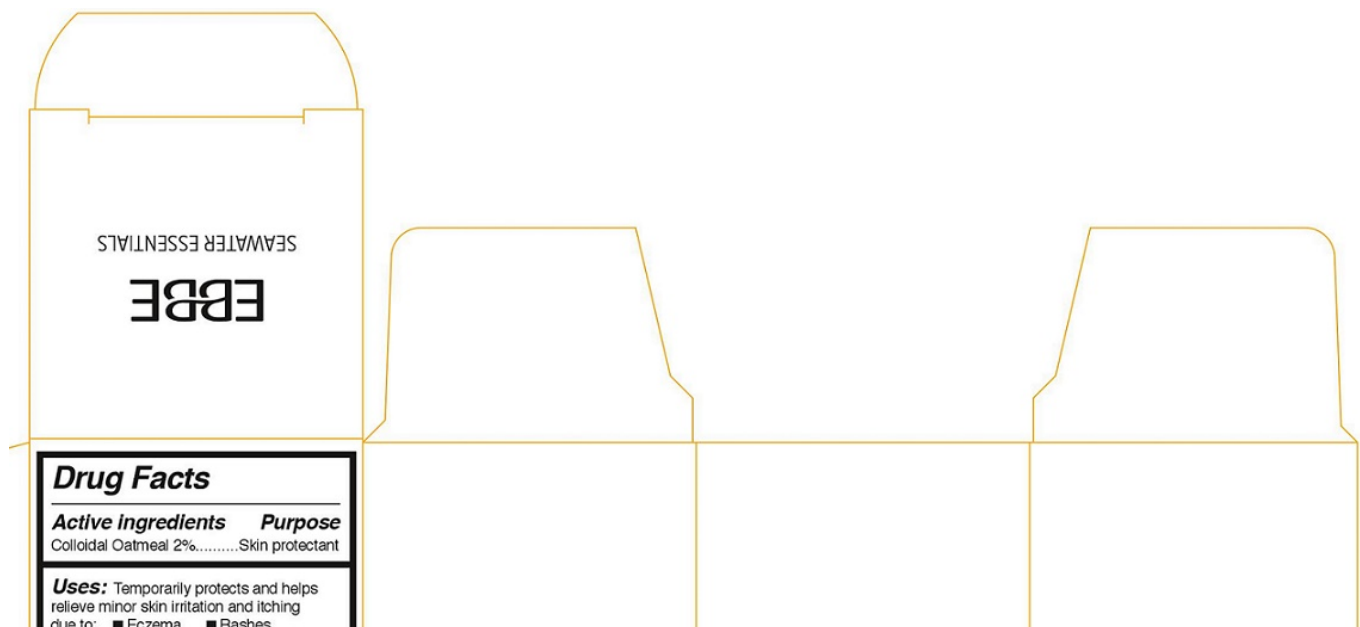
The light texture is absorbed quickly.

Specially indicated for sensitive areas such as face, scalp, and groin.

Suitable for use on adults and children.

Distributed by
Blue Sea Cosmetics Inc.
Tiburon, CA 94920
www.blueseacosmetics.com
Made in Spain

Packaging





EBBE

colloidal oatmeal gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:710 51-10 1
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8 PI54V663Y) (OATMEAL - UNII:8 PI54V663Y)	OATMEAL	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ACETYL HEXAPEPTIDE-49 (UNII: 4055X1S509)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CARBENOXOLONE SODIUM (UNII: F1MP7242Z5)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYALURONIC ACID (UNII: S270N0TRQY)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
EDETATE SODIUM (UNII: MP1J8420LU)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71051-101-02	1 in 1 BOX	11/05/2016	
1	NDC:71051-101-01	100 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	11/05/2016	

Labeler - BLUE SEA LABORATORIES SL. (466819309)

Establishment

Name	Address	ID/FEI	Business Operations
BLUE SEA LABORATORIES SL.		466819309	manufacture(71051-101)

Revised: 11/2016

BLUE SEA LABORATORIES SL.