

XERBEX ECZEMA CREAM- colloidal oatmeal cream
Xerbal USA LLC

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.

Xerbex Eczema Cream

Drug Facts

Active Ingredients	Purpose
Colloidal Oatmeal 1%	Skin Protectant

Uses

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

- rashes
- eczema
- poison ivy, oak, or sumac
- insect bites

Warnings

For external use only

Do not use

- if allergic to any ingredients of this product

When using this product

- do not get into eyes

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days
- symptoms clear up and occur again within a few days
- excessive irritation of the skin develops
- side effects occur. You may report side effects to FDA at 1-800-FDA-1088.

Keep out of reach of children to avoid accidental poisoning .

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply as needed

Other information

- store at room temperature, 20 to 25 °C(68 to 77 °F)

Inactive ingredients

Arlacel 165, Cannabidiol (CBD), Carbomer, Cetareth-20, Cetyl alcohol, Deionized water, Dimethicone, Ethylhexylglycerin, Glycerin, Phenoxyethanol, Phenyl trimethicone, Stearic acid, Sorbitan stearate, Tromethamine, Xanthan Gum

Questions?

Pacific Time 8:00am to 5:00pm

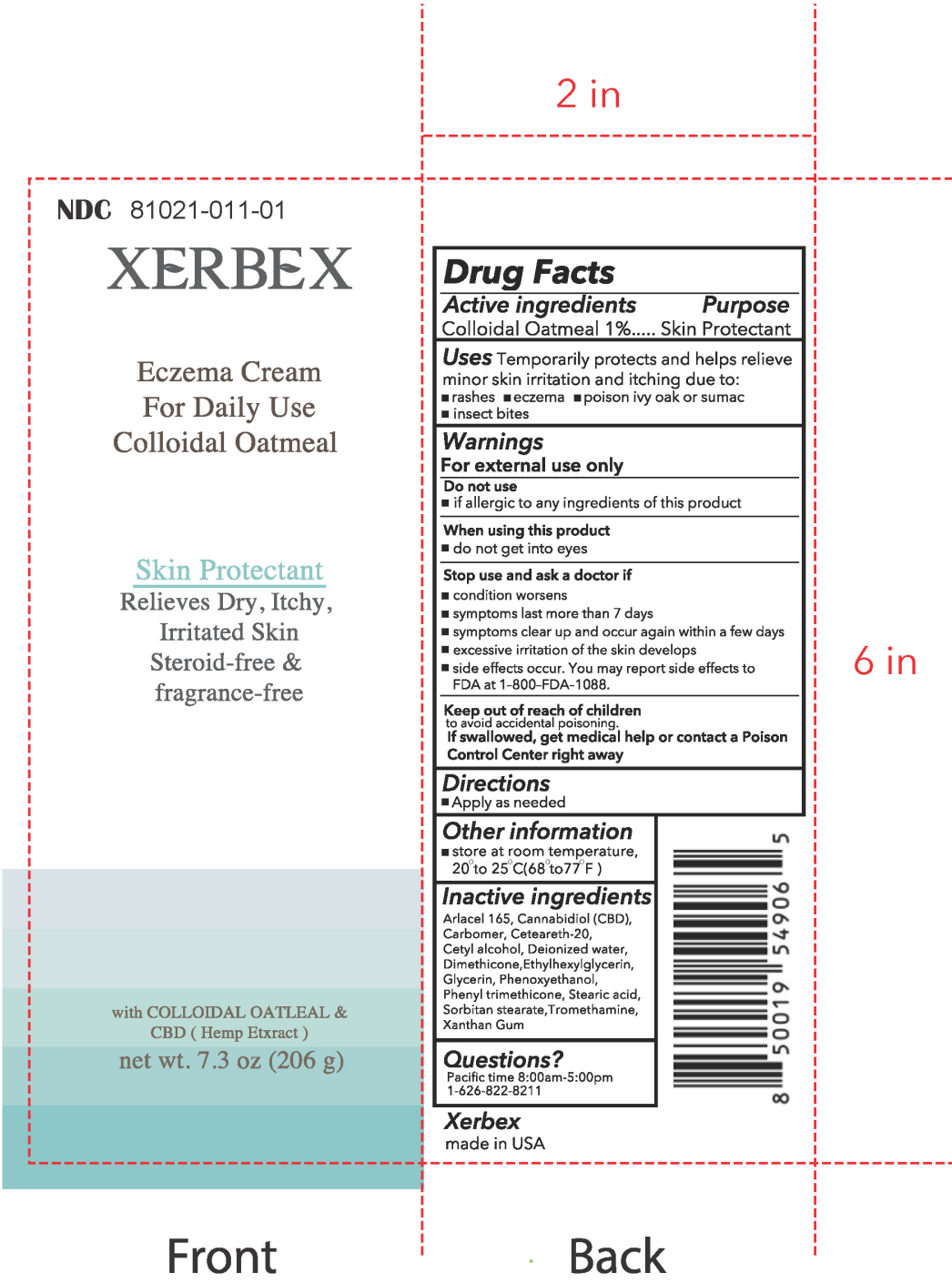
1-626-822-8211

PRINCIPAL DISPLAY PANEL - 7.3 oz (206 g)

NDC.No : 81021-011-01

Xerbex Eczema Cream**Skin Protectant**

Xerbex



colloidal oatmeal cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81021-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERYL STEARATE/PEG-100 STEARATE (UNII: RD25J5V947)	
CANNABIDIOL (UNII: 19GBJ60SN5)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
TROMETHAMINE (UNII: 023C2WHX2V)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81021-011-01	1 in 1 BOX	04/01/2021	
1		206 g 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	04/01/2021	

Labeler - Xerbal USA LLC (117731081)

