PROTOCOXIL- benzyl alcohol gel
Bio Ekuiliber 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.

Protocoxil

Drug Facts

Active ingredients

Benzyl alcohol 10%

Purpose

External analgesic

Use

- for the temporary relief of pain and itching associated with minor skin irritations

Warnings

For external use only

Do not use

- in the eyes

Stop use and ask a doctor if

- condition worsens
- if symptoms persist for more than 7 days
- if symptoms clear up and occur again within a few days

Keep out of reach of children.

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

Directions

- adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: consult a physician

Other information

- protect this product from excessive heat and direct sun

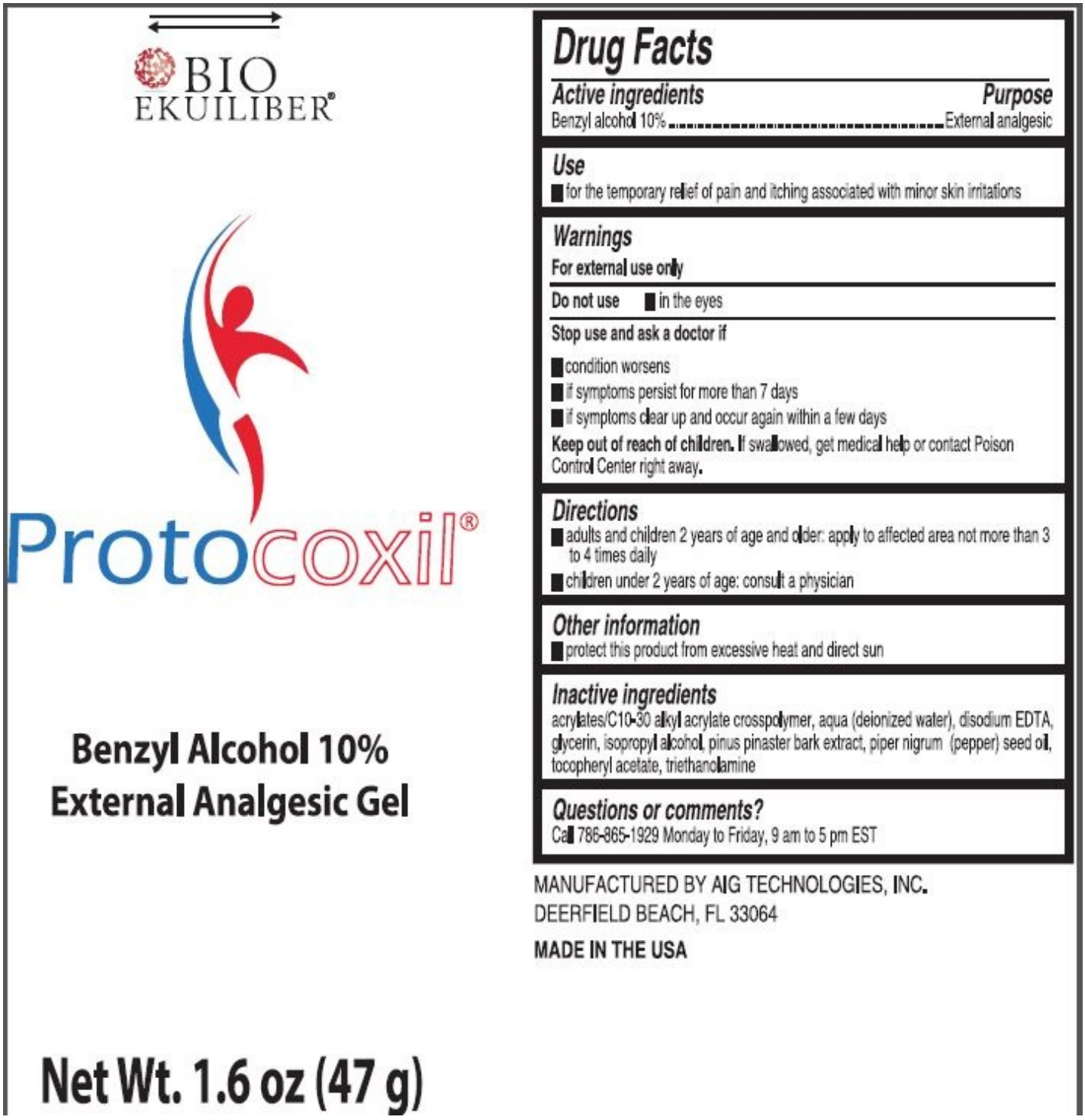
Inactive ingredients

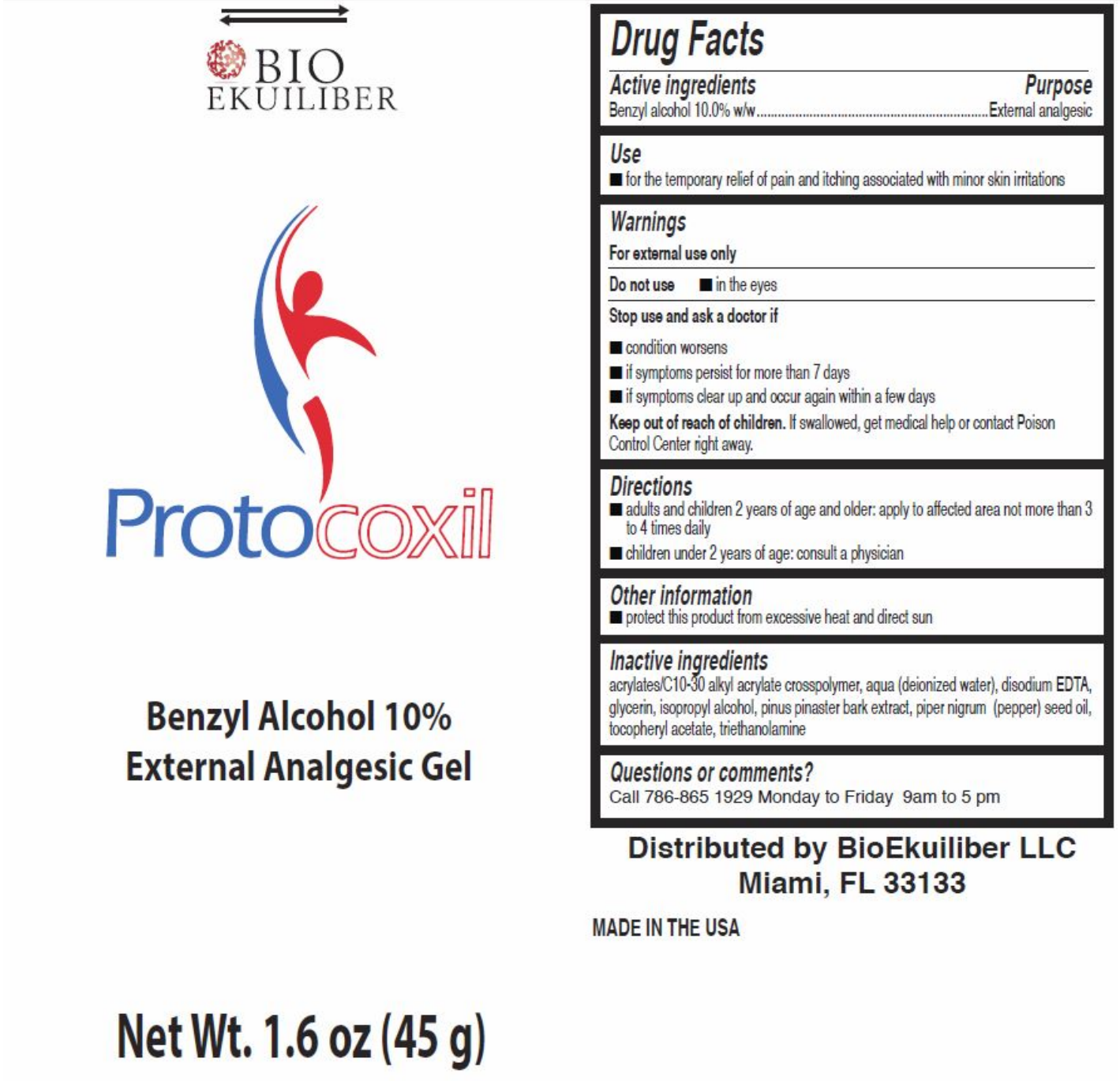
acrylates/C10-30 alkyl acrylate crosspolymer, aqua (deionized water), disodium EDTA, glycerin, isopropyl alcohol, pinus pinaster bark extract, piper nigrum (pepper) seed oil, tocopheryl acetate, triethanolamine

Questions or comments?

Call 786-230-6366 Monday to Friday, 9 am to 5 pm EST

Package Labeling:





PROTOCOXIL

benzyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71416-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZYL ALCOHOL (UNII: LKG8494WBH) (BENZYL ALCOHOL - UNII:LKG8494WBH)	BENZYL ALCOHOL	100 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MARITIME PINE (UNII: 50JZ5Z98QY)	
WHITE PEPPER OIL (UNII: 2AM83DL9FV)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71416-001-00	47 g in 1 BOTTLE; Type 0: Not a Combination Product	05/09/2017	10/07/2019
2	NDC:71416-001-01	45 g in 1 BOTTLE; Type 0: Not a Combination Product	05/09/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/09/2017	

Labeler - Bio Ekuiliber LLC (080648711)

Revised: 11/2020 Bio Ekuiliber LLC