BLT 3- tetracaine ointment
CENTURA PHARMACEUTICALS 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.

ACTIVE INGREDIENT

Tetracaine 2%

PURPOSE

Topical Anesthetic

USES

For the temporary relief of pain and itching.

WARNINGS

• For external use only.
• Avoid contact with eyes or mucus membranes.
• Do not apply to open or damaged skin.
• If condition worsens or symptoms persist for more than seven days, discontinue use and consult physician.
• If pregnant or breast feeding,contact physician prior to use.
• Keep out of reach of children. If swallowed, contact Poison Control Center.
• Do not use if allergic to any ingredient in ointment.
• Do not use in large quantities, particularly over raw surfaces or blistered areas.

DIRECTIONS

Adults and children two-years of age or older: Apply to affected area not more than three to four times daily. Children under two-years of age: consult a physician.

OTHER INFORMATION

Store below 77° F (25° C). Avoid direct sunlight.

INACTIVE INGREDIENTS

Acrylates, C10-30 Alkyl Acrylate Crosspolymer, Aqua (Deionized Water), Beeswax, Benzyl Alcohol, Cetyl Alcohol, Dehydroacetic Acid, Glycerin,

Helianthus Annuus (Sunflower) Oil, Polysorbate 20,
Sodium Hydroxide, Stearic Acid.

KEEP OUT OF REACH OF CHILDREN

PACKAGE LABELING

BLT 3

tetracaine ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70372-729
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TETRACAINE (UNII: 0619F35CGV) (TETRACAINE - UNII:0619F35CGV)	TETRACAINE	2 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
WATER (UNII: 059QF0KO0R)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70372-729-01	5 g in 1 POUCH; Type 0: Not a Combination Product	10/30/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/30/2016	

Labeler - CENTURA PHARMACEUTICALS INC (084921637)

Registrant - CENTURA PHARMACEUTICALS INC (084921637)

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