#### KRT ATHLETIC MUSCLE GEL- trolamine salicylate gel Cosmetic Specialty Labs, 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.

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### **Active Incredient**

Triethanolamine Salicylate 10%

#### Purpose

**Topical analgesic** 

#### Uses

temporarily relieves minor pain associated with • arthritis • simple backache • muscle strains • sprains • bruises • cramps

#### Warnings

for external use only

#### Allergy alert:

If prone to allergic reaction from aspirin or salicylates, consult a doctor before use.

When using this product • use only as directed • avoid contact with eyes or mucous membranes • do not apply to wounds or damaged skin

**Stop use and ask a doctor if** • condition worsens • symptoms persist for more than 7 days or clear up and occur again within a few days • redness is present • irritation develops

If pregnant or breast-feeding, ask a health professional before use.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions:**

Adults and children over 12 years: • apply to affected area • massage into painful area until thoroughly absorbed into skin • repeat as necessary, but no more than 4 times daily

Children 12 years or younger: ask a doctor

## **Inactive Ingredients**

Aloe Barbadensis Leaf Juice, Aminomethyl Propanol, Arnica montana Flower Extract, Butylene Glycol, Caprylyl Clycol, Carbomer, Chamomila recutita (Matricaria) Flower Extract, Citric Acid, Citrus sinensis (Sweet Orange) Peel Oil, Creatine Monohydrate, Fragrance, Lactic Acid, Lauric Acid, Phenoxyethanol, Purified Water, Salvia officinalis (Sage) Extract, Sodium Caprylate, Sorbitol, Triethanolamine.

#### Package Label



# KRT ATHLETIC MUSCLE GEL

trolamine salicylate gel

**Product Information** 

Product Type		HUMAN OTC DRUG	Item Code (So	urce)	NDC:58133-751		
				urce)	100.00100 /01		
Route of Adminis	stration	TOPICAL					
Active Ingredie	ent/Active	Moiety					
	Ingr	edient Name		Basis o Streng	Strendth		
TROLAMINE SALICY UNII:0414PZ4LPZ)	10 g in 100 mL						
Inactive Ingree	dients						
		Ingredient Name			Strength		
CARBOMER 940 (U	NII: 4Q93RCW	27E)					
ANHYDROUS CITRI	C ACID (UNII:	XF417D3PSL)					
TROLAMINE (UNII: 9	O3K93S3TK)						
ORANGE OIL, DIST	LLED (UNII: H	I4QNH2ZN7A)					
SAGE (UNII: 065C5D	077J)						
SODIUM CAPRYLAT	E (UNII: 9XTM	181VK2B)					
BUTYLENE GLYCOL (UNII: 3XUS85KORA)							
CREATINE MONOHYDRATE (UNII: 9603LN7R2Q)							
LACTIC ACID (UNII:	33X04XA5AT)						
CAPRYLYL GLYCOL	(UNII: 00YIU5	438U)					
CHAMOMILE (UNII:	FGL3685T2X)						
ALOE VERA LEAF (L	JNII: ZY81Z83	BHOX)					
LAURIC ACID (UNII:	1160N9NU9U)						
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)							
ARNICA MONTANA							
PHENOXYETHANOL							
WATER (UNII: 059QF		- /					
SORBITOL (UNII: 50							
<b>Product Chara</b>	cteristics						
Color	whit	e (opaque)	Score				
Shape	Size						
Flavor			Imprint C	ode			
Contains							
Packaging							
# Item Code		ckage Description	C	ting Start Date	Marketing End Date		
<b>1</b> NDC:58133-751- 03	89 mL in 1 TL Product	JBE; Type 0: Not a Combinat	tion 03/10/2023	L			
Marketing I	nformat	tion					
Marketing	Applica	ation Number or Monog	graph Mark	eting Start	Marketing End		

Category	Citation	Date	Date
OTC monograph not final	part348	03/10/2021	

# Labeler - Cosmetic Specialty Labs, Inc. (032973000)

Establishment						
Name	Address	ID/FEI	Business Operations			
Cosmetic Specialty Labs, Inc.		032973000	manufacture(58133-751) , label(58133-751) , analysis(58133-751) , pack(58133-751)			

Revised: 8/2021

Cosmetic Specialty Labs, Inc.