TREE FROG- comfrey root, rosemary gel Laboratorios Zepol S.A.

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

Tree frog

Symphytum officinale extract 10X,

Rosmarinus officinale extract 1X.

For Purpose of

Pain Relief

Other ingredients:

Water, Carbomer, Phenoxyethanol (and) Caprylyl Glycol (and) Decylene Glycol, Eucalyptus globulus leaf oil, Gliceryn, Polysorbate 20, Color, Alcohol, Camphor, Menthol, Triethanolamine, Cinnamon aroma.

Directions:

For minor aches and pains. External use only.

For best results, apply two to three times daily as needed.

WARNINGS SECTION

Keep out of reach of children.

Protect from heat. light and moisture. Do not use if safety seal is broken or missing. Do not use with a heating pad. Do not apply to cut, irritated or damaged skin. Do not use on face or near eyes.

Package Labeling:





TREE FROG

comfrey root, rosemary gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55715-007	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
COMFREY ROOT (UNII: M9VVZ08EKQ) (COMFREY ROOT - UNII: M9VVZ08EKQ)	COMFREY ROOT	10 [hp_X] in 1 mL	
ROSEMARY (UNII: IJ67X351P9) (ROSEMARY - UNII:IJ67X351P9)	ROSEMARY	1 [hp_X] in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
CAPRYLYL GLYCOL (UNII: 00YIU5438U)			
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)			

ALCOHOL (UNII: 3K9958V90M)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
TROLAMINE (UNII: 903K93S3TK)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
CINNAMON (UNII: 5S29HWU6QB)	
DECYLENE GLYCOL (UNII: S57M60MI88)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55715- 007-01	120 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/16/2023	

Marketing Information				
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
	05/16/2023			
	Application Number or Monograph	Application Number or Monograph Marketing Start Citation Date		

Labeler - Laboratorios Zepol S.A. (853070985)

Establishment					
Name	Address	ID/FEI	Business Operations		
Laboratorios Zepol S.A.		853070985	manufacture(55715-007)		

Revised: 12/2023 Laboratorios Zepol S.A.