

XCEPTOL PAIN UNSCENTED- tea salicylate cream
XCEPTOR 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.

XCEPTOL PAIN CREAM - UNSCENTED

ACTIVE INGREDIENTS

TEA SALICYLATE 10%

PURPOSE

TOPICAL ANALGESIC

USES

TOPICAL PAIN RELIEF FOR MINOR ACHES AND PAINS.

WARNINGS

FOR EXTERNAL USE ONLY.

KEEP AWAY FROM EYES.

KEEP OUT OF REACH OF CHILDREN.

DIRECTIONS

APPLY SMALL AMOUNT TO AFFECTED AREA AND RUB IN. ADD AS NEEDED.

OTHER INFORMATION

STORE AT 20° - 25°C (68°-77°F)

INACTIVE INGREDIENTS

ALOE BARBADENSIS LEAF JUICE EXTRACT, BENZOIC ACID, BENZYL ALCOHOL, BETA VULGARIS (BEET) ROOT EXTRACT, CANNABIDIOL FROM HEMP, COCOCAPRYLATE/CAPRATE, COCOS NUCIFERA (COCONUT) OIL, COCONUT ALKANES, CYCLODEXTRIN, DISTEARDIMONIUM HECTORITE, GLYCERIN, MAGNESIUM SULFATE, POLYGLYCERYL-3 DIISOSTEARATE, POLYGLYCERYL-3 POLYRICINOLEATE, SHEA BUTTER ETHYL ESTERS, SORBIC ACID, TREMELLA FUCIFORMIS SPOROCARP EXTRACT, XANTHAN GUM, WATER

QUESTIONS / COMMENTS?

PLEASE CALL US AT (760) 710-0510

Drug Facts	<p>Xceptor Labs only uses CBD, or Cannabidiol, sourced from licensed USDA certified Hemp farms and processed at fully permitted and licensed processing facilities. Xceptor Labs verifies the quality of the CBD with an independent certified laboratory. We also test the final product for CBD and Cannabinoid content. When you purchase products made by Xceptor Labs, you can be confident you are purchasing quality products.</p>		<p>The CBD, or Cannabidiol, in product made by Xceptor Labs is different than other CBD on the market. Most CBD products are oil based. Oil does not penetrate the skin easily. Xceptor Labs developed a process to make CBD dispersible in water. This makes the CBD in Xceptol more available for the skin and body.</p>
Active Ingredients Purpose 10.0% Trolamine Salicylate Topical Analgesic			
Uses Topical pain relief for minor aches and pains	1.500	1.500	
Warnings For external use only.			
Allergy alert: If allergic to aspirin or salicylates consult a physician prior to use	<p>*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.</p>	5 MG/ML 1.7 FL OZ (50mL)	<p>Directions: Adults and children 12 yrs and older apply a bead of product over affected area, rub in. Safe to add more for additional relief. Children under 12 consult a physician.</p>
Do not use: - On wounds or damaged skin - With a heating pad - On a child under 12 with arthritis-like conditions - On inflamed skin - With other topical pain relief products When using this product avoid contact with eyes or mucous membranes, avoid exposure to sunlight			
Keep out of reach of children	Directions Adults and children 12 yrs and older apply a bead of product over affected area, rub in. Safe to add more for additional relief. Children under 12 consult a physician.		
Other Information Store at 20°-25° C (68° -77° F)	Questions / Comments? Please call us at (866) 280-0617		NDC 72519-102-22 
Inactive Ingredients Aloe Barbadensis Leaf Juice, Benzoic Acid, Benzyl Alcohol, Betaine, Cannabidiol from Hemp, Cetyl PEG/PPG-10/1 Dimethicone, Coconut Alkanes, Coconut Oil, Cyclodextrin, Dimethicone/Vinyl Dimethicone Crosspolymer, Glycerine, Isododecane, Polyglyceryl-3 Diisostearate, Polyglyceryl-3 Polyrinoleate, Propylene Carbonate, Quaternium-90 Bentonite, Shea Butter Ethyl Esters, Sodium Chloride, Sorbic Acid, Tremella Fuciformis Sporocarp Extract, Water, Xanthan Gum			

XCEPTOL PAIN UNSCENTED

tea salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72519-105
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
TROLAMINE SALICYLATE (UNII: H8O4040BHD) (SALICYLIC ACID - UNII:O414PZ4LPZ)		TROLAMINE SALICYLATE	10 g in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
BENZOIC ACID (UNII: 8SKN0B0MIM)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
BETAINE (UNII: 3SCV180C9W)				
CANNABIDIOL (UNII: 19GBJ60SN5)				
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 1.5) (UNII: V2W71V8T0X)				
COCONUT ALKANES (UNII: 1E5KJY107T)				
COCONUT OIL (UNII: Q9L0O73W7L)				
BETADEX (UNII: JV039JZZ3A)				
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)				
GLYCERIN (UNII: PDC6A3C0OX)				
ISODODECANE (UNII: A8289P68Y2)				
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)				
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)				
PROPYLENE CARBONATE (UNII: 8D08K3S51E)				
QUATERNIUM-91 (UNII: 00J8H295NB)				
SHEA BUTTER ETHYL ESTERS (UNII: V2CI786FPG)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SORBIC ACID (UNII: X045WJ989B)				
TREMELLA FUCIFORMIS FRUITING BODY (UNII: GG8N28393G)				
WATER (UNII: 059QF0KO0R)				
XANTHAN GUM (UNII: TTV12P4NEE)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72519-105-21	30 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/10/2020	
2	NDC:72519-105-22	50 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/10/2020	
3	NDC:72519-105-11	1 mL in 1 PACKET; Type 0: Not a Combination Product	06/10/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	06/10/2020		

Labeler - XCEPTORLLC (081207471)

