EAGLE MEDICATED AROMATIC- camphor menthol methyl salicylate oil Eagle Indo Pharma, PT

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.

Eagle Medicated Oil Aromatic

Active Ingredients

Camphor 7%

Menthol 16% Methyl Salicylate 35%

Purpose

Topical Analgesic

Topical Analgesic

Topical Analgesic

Uses

temporarily relieves the minor aches and pains of muscles and joint associated with \blacksquare simple backache \blacksquare strains

🖬 bruises 🔳 sprains

Warning

For external use only

Do not use

on wounds or damaged skin with a heating pad

Ask a doctor before use if

you have redness over affected area

When using this product

 \blacksquare avoid contact with eyes or mucous membranes \blacksquare do not bandage tightly

Stop use and ask a doctor if

■condition worsens, or if symptoms persist for more than 7 days ■symptoms clear up and occur again within a few days ■ excessive skin irritation occurs

Keep out of reach of children

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

Directions

■ Use only as directed ■ 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: ask a doctor

Inactive ingredients

eucalyptus oil, spike lavender oil, light mineral oil

Question?

1-800-777-6717 or 1-800-645-0769

Package Label



EAGLE MEDICATED AROMATIC

camphor menthol methyl salicylate oil

-	lient/Active	HUMAN OTC DRUG TOPICAL Moiety	ltem Code (Sou	irce)	NDC:60	0954-007
ive Ingred	lient/Active					
-		Moiety				
	Ingredient Name Ba					Strength
			CAMPHOR (SYNTHETIC)		7 g in 100 m	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) ME						16 g in 100 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:0414PZ4LPZ) METHYL SA					CYLATE	35 g in 100 mL
tive Ingr						
		-			St	rength
E LAVENDER	OIL (UNII: 752H	YVIVJQ)				
kaging						
em Code	Pa	ckage Description			Mar	keting End Date
DC:60954- 17-24	1 in 1 BOX		06/20/20	06/20/2022		
	24 mL in 1 BOT Combination Pro	<pre>FLE, GLASS; Type 0: Not a pduct</pre>				
DC:60954- 17-03	1 in 1 BOX		06/20/20	06/20/2022		
	3 mL in 1 BOTT Combination Pro					
DC:60954- 7-08	1 in 1 BOX		06/20/20	06/20/2022		
7-00		E CLASS: Type O: Not a				
-00	8 mL in 1 BOTT Combination Pro	oduct				
DC:60954- 17-12	8 mL in 1 BOTT Combination Pro 1 in 1 BOX	oduct	06/20/20)22		
	HYL SALICYL Ctive Ingra ALYPTUS OIL T MINERAL O E LAVENDER kaging cem Code DC:60954- 7-24	HYL SALICYLATE (UNII: LAV5U Ctive Ingredients ALYPTUS OIL (UNII: 2R040NI6 T MINERAL OIL (UNII: 2R040NI6 T MINERAL OIL (UNII: 2R040NI6 T MINERAL OIL (UNII: 752H) kaging cem Code Pa DC:60954- 7-24 1 in 1 BOX DC:60954- 7-03 1 in 1 BOX DC:60954- 7-03 1 in 1 BOX DC:60954- 7-03 1 in 1 BOX	HYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - U Ingredient Name Ingredient Name ALYPTUS OIL (UNII: 2R040NI662) T MINERAL OIL (UNII: N6K5787QVP) E LAVENDER OIL (UNII: 7S2HYV1VJQ) Kaging Code Package Description OC:60954- 7-24 1 in 1 BOX 24 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product OC:60954- 7-03 1 in 1 BOX	HYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:0414PZ4LPZ) Ingredient Name Ingredient Name ALYPTUS OIL (UNII: 2R040NI662) T MINERAL OIL (UNII: 2R040NI662) T MINERAL OIL (UNII: 7S2HYV1VJQ) E LAVENDER OIL (UNII: 7S2HYV1VJQ) Kaging Seem Code Package Description Market D2:60954- 7-24 1 in 1 BOX 06/20/20 OC:60954- 7-3 1 in 1 BOX 06/20/20 3 mL in 1 BOTTLE, GLASS; Type 0: Not a 06/20/20	AYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:0414PZ4LPZ) METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:0414PZ4LPZ) Ctive Ingredients Ingredient Name Ctive Ingredients Imgredient Name ALYPTUS OIL (UNII: 2R040NI662) Impredient Name T MINERAL OIL (UNII: 2R040NI662) Impredient Name T MINERAL OIL (UNII: 752HYV1VJQ) Impredient Name Kaging Impredient Name Rem Code Package Description DC:60954- 7.24 1 in 1 BOX Inf 1 BOX 06/20/2022 DC:60954- 7.03 1 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product DC:60954- 7.03 1 in 1 BOTTLE, GLASS; Type 0: Not a DC:60954- 7.03 1 in 1 BOTTLE, GLASS; Type 0: Not a	HYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:0414PZ 4LPZ) METHYL SALICYLATE Ctive Ingredients Ingredient Name Str CLYPTUS OIL (UNII: 2R040NI662) Image from the stress of the stress

Marketing Application Number or Monograph

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC monograph not	nort248	06/20/2022	

Labeler - Eagle Indo Pharma, PT (728682519)

Establishment								
Name	Address	ID/FEI	Business Operations					
Eagle Indo Pharma, PT		728682519	manufacture(60954-007)					

Revised: 6/2022

Eagle Indo Pharma, PT