ANTIPHLAMINE COIN PLASTER- methyl salicylate(kp) 5.541mg, l-menthol(kp), 2.769mg, dl-camphor(kp), 1.108mg, mentha oil(kp) 0.693mg, tocopherol acetate(kp) 0.308mg, diphenhydramine(kp) 0.246mg, vanillyl nonylamide(in-house) 0.046mg patch Hanul Trading Co., Ltd.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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## ACTIVE INGREDIENT

Active Ingredient: Methyl salicylate(KP) 5.541mg, L-menthol(KP), 2.769mg, dl-camphor(KP), 1.108mg, Mentha Oil(KP) 0.693mg, Tocopherol Acetate(KP) 0.308mg, Diphenhydramine(KP) 0.246mg, Vanillyl nonylamide(In-house) 0.046mg

## **INACTIVE INGREDIENT**

[Inactive Ingredients] Hydrogenated C6-20 Polyolefin, Styrene isoprene styrene block copolymer, Liquid paraffin, Polyisobutylene, Butylated hydroxytoluene, Non-woven fabric, Polyethylene terephthalate separator

#### **PURPOSE**

[Purpose] Topical Analgesic

# **Warnings and Precautions**

[Warnings and Precautions] 1. Do not use to following patients 1) Children under 30 months 2) Patients with wounds or damaged skin cause by eczema or poison ivy

- 2. Use carefully when using to following patients 1) Patients who have a history of allergic reaction to any drug or cosmetics 2) Patients who are allergic or whose family is allergic 3) Patients with severe moistness or erosion 4) Patients who are under a doctor's cure 5) Infant (Convulsions may occur)
- 3. Side effects 1) Stop using and ask doctor or pharmacist if rash, redness, itching, or edema occurs. 2) Stop using if sometimes severe itching or pain occurs.
- 4. General Precautions 1) Follow the given dosage and administration. 2) Use under adult's care for children. 3) Stop using and ask doctor or pharmacist if there is no improvement of symptoms in 5~6 days of using.
- 5. Precautions for application 1) For external use only. 2) Use after wiping if the affected part is wet. 3) Do not heat the affected part with electric blanket or any. 4) Do not take a bath with this drug attached. Remove it 30 min~1 hour before bath.
- 6. Precautions for storage 1) Keep out of the reach of children. 2) Store in a cool place out of direct sunlight, and keep it sealed. 3) Avoid misuse and do not put this product in a separate container for preservation of quality.

#### KEEP OUT OF REACH OF CHILDREN

KEEP OUT OF REACH OF CHILDREN

#### **Indications**

[Indications] Anti-inflammatory effect to following symptoms: Bruise, wrick, muscle pain, arthralgia, backache, shoulder pain, neuralgia, and rheumatic pain.

#### **DOSAGE & ADMINISTRATION**

[Dosage and Administration] Put the product on the affected part, one~several sheets daily

#### OTHER SAFETY INFORMATION

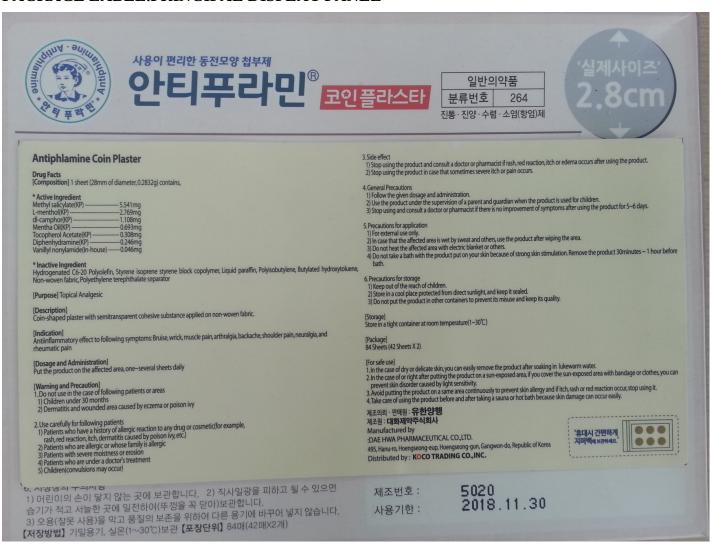
[Description] Coin-shaped plaster with semitransparent cohesive substance applied on non-woven fabric.

[Storage] Store in tight container at room temperature(1~301)

[Package] 84 Sheets (42 Sheets X 2)

[Safe Administration] 1. If attached to dry or delicate skin, use lukewarm water when removing. 2. If attached to sun-exposed part, you can prevent extraordinary skin reaction by covering the part with a bandage or clothes. 3. Avoid using it to the same part continuously to prevent skin allergy. Stop using if itching, rash, or redness occurs. 4. Take care to avoid using before and after taking a sauna or hot massage.

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



# ANTIPHLAMINE COIN PLASTER

methyl salicylate(kp) 5.541mg, l-menthol(kp), 2.769mg, dl-camphor(kp), 1.108mg, mentha oil(kp) 0.693mg, tocopherol acetate(kp) 0.308mg, diphenhydramine(kp) 0.246mg, vanillyl nonylamide(in-house) 0.046mg patch

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69642-1600	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
LEVOMENTHOL (UNII: BZ1R15MTK7) (LEVOMENTHOL - UNII:BZ1R15MTK7)	LEVOMENTHOL	2.769 mg in 0.2832 g		
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	1.108 mg in 0.2832 g		
Diphenhydramine (UNII: 8GTS82S83M) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	Diphenhydramine	0.246 mg in 0.2832 g		
.ALPHATOCOPHEROL, DL- (UNII: 7QWA1RIO01) (.ALPHATOCOPHEROL, DLUNII:7QWA1RIO01)	.ALPHA TOCOPHEROL, DL-	0.308 mg in 0.2832 g		
Methyl Salicylate (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	Methyl Salicylate	5.541 mg in 0.2832 g		
Peppermint oil (UNII: AV092KU4JH) (PEPPERMINT - UNII:V95R5KMY2B)	PEPPERMINT	0.693 mg in 0.2832 g		
Nonivamide (UNII: S846B891OR) (NONIVAMIDE - UNII:S846B891OR)	Nonivamide	0.046 mg in 0.2832 g		

Inactive Ingredients		
Ingredient Nam	e	Strength
MINERAL O IL (UNII: T5L8T28FGP)		

]	Packaging				
7	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
:	NDC:69642-1600-2	84 in 1 CARTON	10/10/2016		
:	NDC:69642-1600-1	0.2832 g in 1 PATCH; Type 0: Not a Combination Product			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
unapproved drug other		10/10/2016			

Labeler - Hanul Trading Co., Ltd. (689512982)

**Registrant -** Hanul Trading Co., Ltd. (689512982)

# **Establishment**

Name	Address	ID/FEI	<b>Business Operations</b>
Hanul Trading Co., Ltd.		689512982	relabel(69642-1600)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
DAE HWA PHARMACEUTICAL CO., LTD.		688004324	manufacture(69642-1600)

Establishment			
Name	Address	ID/FEI	Business Operations
KOCO TRADING CO., INC.		079457993	repack(69642-1600)

Revised: 5/2017 Hanul Trading Co., Ltd.