

PO SUM ON HEALING BALM- menthol ointment
PO SUM ON MEDICINE FACTORY LIMITED

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.

DRUG FACTS

Active ingredients
Menthol 13%

Purpose
External analgesic

Uses

For the temporary relief of minor aches and pains of muscles and joints due to:
simple backache
arthritis
sprains
bruises
sprains

Warnings

For external use only

Do not use
on wounds

on damaged skin
if excessive irritation develops

When using this product
avoid contact with the eyes
do not bandage tightly

Stop use and ask a doctor if
condition worsens
symptoms persist for more than 7 days
symptoms clear up and occur again within a few days
when using for pain of arthritis if:
 pain persists for more than 10 days
 redness is present
 in conditions affecting children under 12 years of age

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

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: Do not use, consult your doctor.

Other information

keep container tightly closed
store at 15 to 30C (59 to 86F)

Inactive ingredients

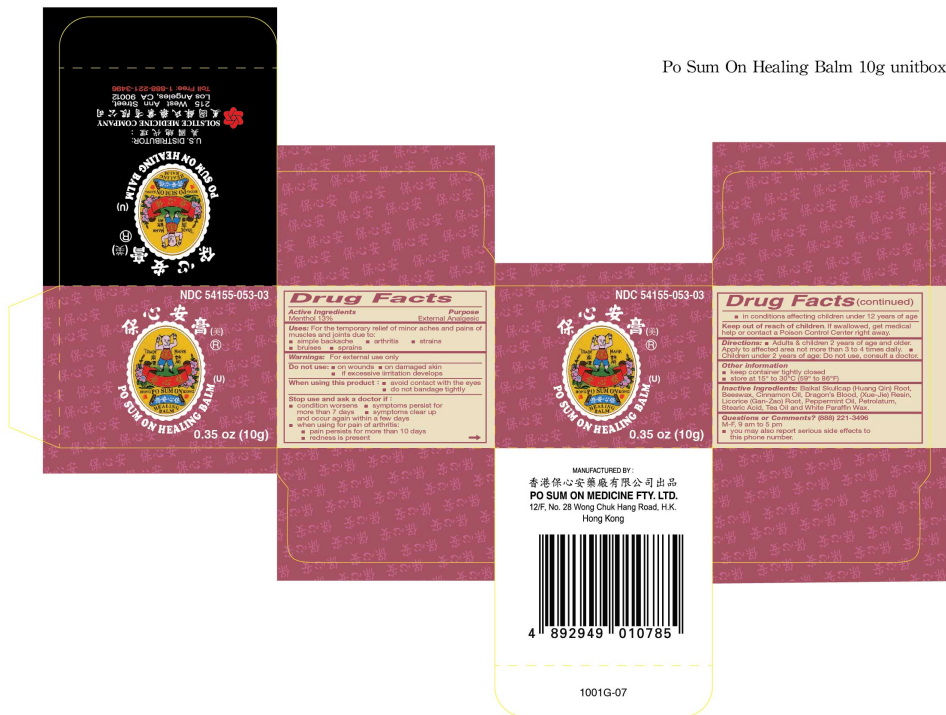
Baikal Skullcap (Huang-Qin) Root, Beeswax, Cinnamon Oil, Dragon's Blood (Xue-Jie) Resin, Licorice (Gan-Zao) Root, Peppermint Oil, Petrolatum, Stearic Acid, Tea Oil and White Paraffin Wax.

Questions or comments? (888)221-3496 M-F 9am to 5pm
you may also report serious side effects to this phone number

PO SUM ON HEALING BALM

NDC 54155-053-03

0.35 oz (10g)



PO SUM ON HEALING BALM

menthol ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54155-053
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	13 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CINNAMON OIL (UNII: E5GY4I6YCZ)	
DAEMONOROPS DRACO RESIN (UNII: 787Z7N9UCU)	
GLYCYRRHIZA URALENSIS WHOLE (UNII: 8XW1DS8UIR)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
PETROLATUM (UNII: 4T6H12BN9U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CAMELLIA OIL (UNII: T1PE06G0VE)	
PARAFFIN (UNII: I9O0E3H2ZE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54155-053-02	1 in 1 BOX	05/25/2017	
1		18 g in 1 JAR; Type 0: Not a Combination Product		
2	NDC:54155-053-03	1 in 1 BOX	05/25/2017	
2		10 g in 1 JAR; Type 0: Not a Combination Product		
3	NDC:54155-053-01	1 in 1 PACKET	08/22/2019	
3		3.5 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/25/2017	

Labeler - PO SUM ON MEDICINE FACTORY LIMITED (664986395)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 8/2019

PO SUM ON MEDICINE FACTORY LIMITED