HAMSOA YUYU DERMA119 BALM- witch hazel cream HAMSOA PHARMACEUTICAL CO., LTD.

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.

ACTIVE INGREDIENT

Active ingredients: Witch hazel (Hamamelis Virginiana) 0.1%

INACTIVE INGREDIENT

Inactive ingredients:

Water, Cocamidopropyl Betaine, Lauryl Glucoside, Potassium cocoyl glycinate, TEA-Cocoyl Glutamate, Cocamide Methyl MEA, Citrus Unshiu Fruit Oil, Polyquaternium-10, Polyquaternium-7, Citrus Aurantium Dulcis (Orange) Oil, Citrus Medica Limonum (Lemon) Fruit Oil, Caprylhydroxamic Acid, Caprylyl Glycol, Glycerin, Betaine, Disodium EDTA, Caramel, Glycyrrhiza Glabra (Licorice) Root Extract, Phaseolus Radiatus Seed Extract, Paeonia Albiflora Root Extract, Paeonia Suffruticosa Root Extract, Sophora Angustifolia Root Extract, Foeniculum Vulgare (Fennel) Fruit Extract, Lavandula Angustifolia (Lavender) Extract, Ocimum Basilicum (Basil) Leaf Extract, Althaea Officinalis Root Extract, Houttuynia Cordata Extract, Anthemis Nobilis Flower Extract,

Althaea Officinalis Root Extract, Houttuynia Cordata Extract, Anthemis Nobilis Flower Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Panthenol, Prunus Persica (Peach) Leaf Extract, Salix Alba (Willow) Bark Extract, Morus Alba Root Extract, Broussonetia Extract, Sophora Japonica Leaf Extract, Lactobacillus Ferment, Scutellaria Baicalensis Root Extract, Camellia Sinensis Leaf Extract, Artemisia Princeps Leaf Extract, Houttuynia Cordata Extract, Citrus Junos Fruit Extract, Ricinus Communis (Castor) Seed Oil, Portulaca Oleracea Extract, Citric Acid, Squalane

PURPOSE

Purpose: Hair and body wash

WARNINGS

Warnings

- 1. Stop use immediately if the following symptoms occur, and consult a dermatologist.
- A) If use of the product causes red spots, swelling, itching, or other irritation
- B) If direct sunlight causes the symptoms listed above
- 2. Do not use on areas of injury, rash, or skin inflammation.
- 3. Keep out of eyes when using the products. Immediately rinse with water in case of eye contact.
- 4. Thoroughly rinse with water after use on hair to avoid hair loss or bleaching.
- 5. Storage and safety precautions
- A) Close lid tightly when not in use.
- B) Keep out of reach of children and infants.
- C) Do not store in high/low temperatures, and keep away from sunlight.
- 6. Try patch test on small area of skin before use or when switching to a new product.
- 7. Do not place product contents back into container after use to avoid deterioration of quality.
- 8. This is a cosmetic product not intended to be used by children.

INDICATIONS AND USAGE

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Use an appropriate amount and lather well. Gently massage onto body and hair, and rinse thoroughly

KEEP OUT OF REACH OF CHILDREN

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DOSAGE AND ADMINISTRATION

Recommended amount per use: 1-2g

PACKAGE LABEL. PRINCIPAL DISPLAY PANEL



HAMSOA YUYU DERMA119 BALM

witch hazel cream

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:50964-060 Route of Administration TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
WITCH HAZEL (UNII: 10 114J0 U34) (WITCH HAZEL - UNII:10 114J0 U34)	WITCH HAZEL	0.009 g in 9 g

Inactive Ingredients	
Ingredient Name	Strength
JOJOBA OIL (UNII: 724GKU717M)	
CERESIN (UNII: Q1LS2UJO3A)	
MICRO CRYSTALLINE WAX (UNII: XOF597Q3KY)	
SHEA BUTTER (UNII: K49 155WL9 Y)	
CYCLOMETHICONE (UNII: NMQ347994Z)	

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50964-060-01	9 g in 1 CARTON		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/01/2012	

Labeler - HAMSOA PHARMACEUTICAL CO., LTD. (690417753)

Registrant - HAMSOA PHARMACEUTICAL CO., LTD. (690417753)

Establishment			
Name	Address	ID/FEI	Business Operations
HAMSOA PHARMACEUTICAL CO., LTD.		690417753	manufacture(50964-060)

Revised: 8/2012 HAMSOA PHARMACEUTICAL CO., LTD.