

HEIBAITONG PAIN RELIEVING PATCH- menthol, camphor patch
Harbin Kangyou Pharmaceutical Limited Company

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.

Harbin Kangyou Pharmaceutical Limited Company

ACTIVE INGREDIENTS

Menthol 5%

Camphor 3.5%

PURPOSE

Menthol External Analgesic

Camphor External Analgesic

USES

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

Warnings

For External Use only.

Do not use

on wounds.
on irritated or damaged skin.
if the appearance of this product has changed.
in excess of 12 hours.
if you are hypersensitive to this product.
otherwise than as directed.

ASK A DOCTOR OR PHARMACIST BEFORE USE IF YOU ARE

pregnant.
taking other medications.

When using this product

avoid contact with the eye or mucous membranes.
do not bandage tightly.
supervise use by children.
use caution if prone to allergic reactions.

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.
excessive irritation of the skin develops.
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 12 years of age and older: This product can be applied up to 168 hours of repeated uses. Remove the package from package. Heat up the patch until it easily gets separated and it becomes soft and glossy (avoid touching on skin when it is hot from the heat). Apply one or two patches to affected area once a day. Remove after every 6-12 hours depending on symptoms. During treatments, it is normal to feel the heat from patch itself. It can be removed anytime if discomfort occurs. Children 2 to 12 years of age and adults with compromised health: Use only under the guidance of a doctor. Children under 2 years of age: Do not use, consult a doctor. Refer to the above warnings: use otherwise than as directed may be dangerous.

Other Information

Keep container tightly closed.
Store below 20 ° (68 °) in a dry area.

Inactive Ingredients

NOTOPTERYGIUM INCISUM ROOT, ANGELICA PUBESCENS ROOT, SINOMENIUM ACUTUM STEM, PERIPLOCA SEPIUM ROOT BARK, SAPOSHNIKOVIA DIVARICATA ROOT, ATRACTYLODES LANCEA ROOT, CNIDIUM MONNIERI FRUIT, ALPINIA OFFICINARUM WHOLE, CUMINUM CYMINUM WHOLE, CINNAMON, ANGELICA SINENSIS ROOT, PAEONIA LACTIFLORA ROOT, PAPAYA, CAESALPINIA SAPPAN WOOD, RHUBARB, PINUS TABULIFORMIS BARK, DIPSACUS CHINENSIS WHOLE, LIGUSTICUM WALLICHII ROOT, ANGELICA DAHURICA ROOT, FRANKINCENSE OIL, MYRRH, BORNEOL, CLOVE OIL, CHINESE CINNAMON, CINNAMOMUM CASSIA TWIG, PANAX NOTOGINSENG ROOT, SAFFRON, ERYCIBE OBTUSIFOLIA STEM, PIPER KADSURA STEM, FOSSILIZED MAMMAL BONE

Questions or Comments?

Relief Saturated LLC
Alhambra, California 91801

Call (626) 247-0304 or
E-mail: kyle.hsieh18@gmail.com

Manufactured by

Kangyou Pharmaceutical Limited Company
2nd Building, 1st Floor, 8 Km Half of Ha Double Highway in Dao Li District
Harbin 150076, China

Distributed by
 Relief Saturated LLC
 Alhambra, California 91801 USA

Drug Facts

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Active ingredients	Purpose
Menthol 5%.....	External Analgesic
Camphor 3.5%.....	External Analgesic

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- If you are hypersensitive to this product
- Otherwise than as directed

Ask a doctor or pharmacist before use if you are

- Pregnant
- Taking other medication

When using this product

- Avoid contact with the eyes or mucous membranes
- Do not bandage tightly
- Supervise use by children
- Use caution if prone to allergic reactions

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
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Other information

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Inactive ingredients
 Notopterygium laetum Root, Angelica Pubescens Root, Sinomenium Acutum Stem, Periploca Sepium Root Bark, Saposhnikovia Divaricata Root, Atractylodes Lancea Root, Cnidium Monnieri Fruit, Alpinia Officinarum Whole, Cumlaunum Cyninum Whole, Cinnamon, Angelica Sienensis Root, Peconia Lactiflora Root, Papaya, Caesalpinia Sappan Wood, Rhubarb, Pinus Tabulliformis Bark, Diosacus Chinesis Whole, Ligusticum Wallichii Root, Angelica Dahurica Root, Frankincense Oil, Myrrh, Borneol, Clove Oil, Chinese Cinnamon, Cinnamomum Cassia Twig, Panax Notoginseng Root, Saffron, Erycibe Obasifolia Stem, Piper Kadsura Stem, Fossilized Mammal Bone

Questions or comments?
 Relief Saturated LLC
 Alhambra, California 91801
 Call (626) 247-0304 or
 E-mail: kyle.hsieh19@gmail.com

Manufactured by:
 Harbin Kangyou Pharmaceutical Limited Company Lot #
 2nd Building, 1st Floor, 8 Km Half of He Double Highway Exp. Date:
 24 Dui Li District Harbin 150076, China
Distributed by:
 Relief Saturated LLC
 Alhambra, California USA 91801

HEIBAITONG PAIN RELIEVING PATCH

menthol, camphor patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72328-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5.0 g in 100 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	3.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
NO TOPTERYGIUM INCISUM ROOT (UNII: 5Z2WW4J6RI)	
ANGELICA PUBESCENS ROOT (UNII: 0MF1EI01KJ)	
SINOMENIUM ACUTUM STEM (UNII: BBH96IEM66)	
PERILOCA SEPIUM ROOT BARK (UNII: 638OW484M3)	
SAPOSHNIKOVIA DIVARICATA ROOT (UNII: 8H84LFK2QD)	
ATRACTYLODES LANCEA ROOT (UNII: CAZ6282J2O)	
CNIDIUM MONNIERI FRUIT (UNII: V1IA3S3CUS)	
ALPINIA OFFICINARUM WHOLE (UNII: 6D24820XKG)	
CUMINUM CYMINUM WHOLE (UNII: 5BD8A7OW68)	
CINNAMON (UNII: 5S29HWU6QB)	
ANGELICA SINENSIS ROOT (UNII: B66F4574UG)	
PAEONIA LACTIFLORA ROOT (UNII: 3Z3866YW6P)	
PAPAYA (UNII: KU94FIY6JB)	
CAESALPINIA SAPPAN WOOD (UNII: 086263LQDD)	
RHUBARB (UNII: G280W4MW6E)	
PINUS TABULIFORMIS BARK (UNII: 3G75L8C3RU)	
DIPSACUS CHINENSIS WHOLE (UNII: O6JK1ZU9NN)	
LIGUSTICUM WALLICHII ROOT (UNII: R81AD159QS)	
ANGELICA DAHURICA ROOT (UNII: 1V63N2S972)	
FRANKINCENSE OIL (UNII: 67ZYA5T02K)	
MYRRH (UNII: JC71GJ1F3L)	
BORNEOL (UNII: M89NIB437X)	
CLOVE OIL (UNII: 578389D6D0)	
CHINESE CINNAMON (UNII: WS4CQ062KM)	
CINNAMOMUM CASSIA TWIG (UNII: 4UD6VQR2UP)	
PANAX NOTOGINSENG ROOT (UNII: GQX1C1175U)	
SAFFRON (UNII: E849G4X5YJ)	
ERYCIBE OBTUSIFOLIA STEM (UNII: V1G1S38CQI)	
PIPER KADSURA STEM (UNII: 80IOP41EL7)	
MAMMAL BONE, FOSSILIZED (UNII: 0N1T3913DA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72328-001-01	1 in 1 POUCH	07/23/2018	
1		13 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
OTC monograph not final	part348	07/23/2018	

Labeler - Harbin Kangyou Pharmaceutical Limited Company (554409031)

Registrant - Harbin Kangyou Pharmaceutical Limited Company (554409031)

Establishment

Name	Address	ID/FEI	Business Operations
Harbin Kangyou Pharmaceutical Limited Company		554409031	manufacture(72328-001)

Revised: 12/2018

Harbin Kangyou Pharmaceutical Limited Company