## PROSTADERM- camphor plaster EZP Corporation

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.

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### **Prostaderm**

Active ingredients Purpose

Camphor 3%.....External analgesic

**Uses** For the temporary relief of pain

### When using this product

- Do not exceed recommended dosage
- Do not use otherwise than as directed
- Do not apply to wounds or damaged skin

### 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
- side effects occur. You may report side effects to FDA at 1–800–FDA–1088.

**If pregnant or breast-feeding,** ask a health professional before use.

Keep this and all drugs out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away Do not use otherwise than as directed

• Questions?1-877-806-3569

### **Directions**

- Clean and dry affected area
- Cut open pouch and remove patch
- Remove Protective film and apply directly to the navel vertically
- Do not apply to area with excessive hair. Highly adhesive patch, may hurt skin upon removal

Adults	Apply to affected area for 24-48 hours	
Children under 18 years of age	Ask a doctor	

### For external use only.

### Do not use otherwise than as directed

**Uses** For the temporary relief of pain.

Cistanche Deserticola stem, Syzygium aromaticum whole, Commiphora myrrha resin, Corydalis bungeana whole, Dictamnus dasycarps root bark, Foeniculum vulgare whole, Synthetic moschus resin, Polyvinyl alcohol, Glycerol, Laurocapram

### **Prostaderm PDP**



# **External Analgesic Patch**

For External Use Only

Net Content: 1 Patch 1 1/16 in x 2 1/4 in (26 mm x 57 mm)

### **Prostaderm Drug Facts**

#### Drug Facts (continued) **Drug Facts** If pregnant, ask a health professional before use. Keep out of reach of children to avoid accidental poisoning, In case of overdose, get medical help or contact a Poison Control Center right away Active ingredients **Purpose** Camphor 3%.....External analgesic Uses For the temporary relief of pain Do not use otherwise than as directed Warnings Directions For external use only ■ Clean and dry affected area Do not use ■ Cut open pouch and remove patch ■ on wounds ■ irritated or damaged skin ■ sensitive skin ■ with a heating pad ■ if pregnant ■ Remove protective film and apply directly to the maver vertically Bo not apply to area with excessive hair. Adhesive plaster may hurt skin upon removal. Adults Apply to affected area for 24-48 hours. Children under Ask a doctor with, or as the same time as, other external analgesic products ■ if allergic to aspirin or salicylate ■if allergic to any ingredients of this product When using this product 18 years of age ■Do not exceed recommended dosage Other information ■ Do not use otherwise than as directed ■ store unused patch in the pouch ■ store at room temperature, 20° to 25°C(68° to 77°F) ■Do not apply to wounds or damaged skin Stop use and ask a doctor if ■ condition worsens ■ symptoms persist for more than 7 days Inactive ingredients Cistanche Deserticola stem. Syzygium aromaticum whole, Commiphora myrrha resin, Corydalis bungeana whole, Dictamnus dasycarps root bark, ■symptoms clear up and occur again within ■excessive irritation of the skin develops Foeniculum vulgare whole, Synthetic moschus resir redness is present Polyvinyl alcohol, Glycerol, Laurocapram ■ side effects occur. You may report side effects to FDA at 1–800–FDA–1088. Questions? 1-877-806-3569

Distributed by: EZP Inc. 179 West Route 46 Suite 9-158 Rockaway, NJ 07866 USA

www.prostaderm.com | Tel. 1-877-806-3569 | Fax. 1-888-349-5369

### **PROSTADERM**

camphor plaster

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69446-100
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET) CAMPHOR (SYNTHETIC) 3 in 100

Inactive Ingredients		
Ingredient Name	Strength	
CISTANCHE DESERTICO LA STEM (UNII: 45BEI4ZF64)		
SYZYGIUM ARO MATICUM WHO LE (UNII: EY9 MMA 0 P6 Y)		
COMMIPHORA MYRRHA WHOLE (UNII: UU8 1N77RI7)		
CORYDALIS BUNGEANA WHOLE (UNII: 732H9 A883V)		
DICTAMNUS DAS YCARPUS ROOT BARK (UNII: LA97176 ILS)		
FOENICULUM VULGARE WHOLE (UNII: J1UK54JBGH)		
MOSCHUS MOSCHIFERUS MUSK SAC RESIN (UNII: 8KFK4W7KP7)		
POLYVINYL ALCOHOL (UNII: 532B59J990)		
GLYCEROL FORMAL (UNII: 3L7GR2604E)		
LAURO CAPRAM (UNII: 1F3X9 DRV9 X)		

]	Packaging			
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69446-100-01	1 in 1 PACKAGE	02/24/2015	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	0 2/24/20 15	

### Labeler - EZP Corporation (039212541)

### **Registrant** - Jinzhou Zijing Pharmaceutical Co. (527929247)

Establishment				
Name	Address	ID/FEI	Business Operations	
Jinzhou Zijing Pharmaceutical Co., Ltd.		527929247	manufacture(69446-100)	

Revised: 2/2015 EZP Corporation