ASTRAPHARM CHILLI BRAND EXTERNAL MEDICATED- capsaicin plaster DERSAN 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.

DRUG FACTS

Active ingredients

Capsaicin 0.25%

Purpose

External analgesic

Uses Temporarily relieves minor aches and pains of muscles and joints due to:

- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

For external use only

Allergy alert: This product contains natural rubber latex which may cause allergic reactions

Do not use

- on wounds
- on irritated or damaged skin

When using this product

- avoid contact with the eyes or mucous membranes
- do not bandage tightly

Stop use and ask a doctor if

- excessive irritation of the skin develops
- Condition worsens
- Isymptoms 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
 - if 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

- Peel apart from paper backing and apply directly to the affected area. If needed, cut plaster into small pieces and apply to affected area. It will be more effective when used after a bath.
- Adults and children 2 years and older: Apply to affected area no more than 3 to 4 times daily.
- Children under 2 years: Do not use, consult a doctor.

Other information

- Not recommended for people with sensitive skin. May cause rash or festering.
- Not recommended for use when in contact with hot water. Burning sensation may occur.
- Do not apply on extremely hairy surface of skin. Highly adhesive plaster may hurt skin upon removal of product.
- Preserve in tight container after opening.
- Store at 20-25°C (68-77°F)

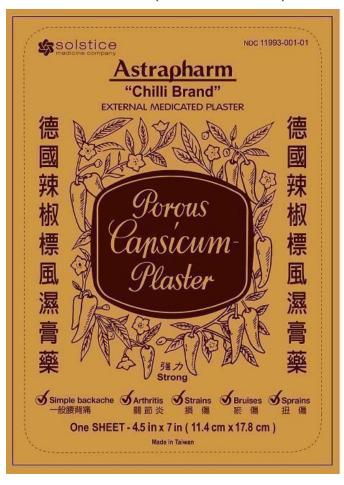
Inactive ingredients Beta-pinene homopolymer, calcium carbonate, light steam-cracked aromatic naphtha (petroleum), polybutenes, rubber (natural), synthetic iron oxide, and zinc oxide.

Questions or comments? (888) 221-3496 M-F 9 am to 5 pm

• you may also report serious side effects to this phone number

ASTRAPHARM CHILLI BRAND EXTERNAL MEDICATED PLASTER NDC 11993-001-01

Simple backache, Arthritis, Strains, Bruises, Sprains 1 Sheet - 4.5 in x 7 in (11.4 cm x 17.8 cm)

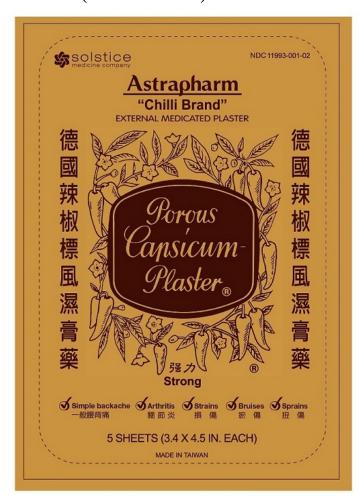




ASTRAPHARM CHILLI BRAND EXTERNAL MEDICATED PLASTER

NDC 11993-001-02

Simple backache, Arthritis, Strains, Bruises, Sprains 5 Sheets - (3.4 x 4.5 in Each)





ASTRAPHARM CHILLI BRAND EXTERNAL MEDICATED

capsaicin plaster

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11993-001	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	70 mg	

Inactive Ingredients	
Ingredient Name	Strength
.BETAPINENE (UNII: 4MS8VHZ1HJ)	
CALCIUM CARBO NATE (UNII: H0 G9 379 FGK)	

NAPHTHA (UNII: O3L624621X)	
POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)	
NATURAL LATEX RUBBER (UNII: 2LQ0 UUW8 IN)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:11993-001-01	24 in 1 BOX	05/01/2007	
1	1 in 1 POUCH; Type 0: Not a Combination Product		
2 NDC:11993-001-02	10 in 1 BOX	05/01/2007	
2	5 in 1 POUCH; 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	05/01/2007	

Labeler - DERSAN PHARMACEUTICAL CO LTD (657669362)

Establishment				
Name	Address	ID/FEI	Business Operations	
DERSAN PHARMACEUTICAL CO LTD		657669362	manufacture (11993-001)	

Revised: 6/2017 DERSAN PHARMACEUTICAL CO LTD