AGERANIUM PATCH- capsaicin patch
Entom 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.

Ageranium Patch

Active ingredient

Capsacin 0.228mg

Purpose

External analgesic

Uses

For temporary relief of minor aches & pains of muscles & joints associated with:

- arthritis
- simple backace
- strains
- bruises
- sprains

Warnings

For external use only

Allergy alert: If prone to have an allergic reaction to Capsaicin, cunsult a doctor before use.

Do not use

- on wounds or damaged skin
- if you are allergic to any ingredients of this product

When using this product

- use only as directed
- avoid contact with the eyes, mucous membran, and rashes
- wrap the bandage not too tight

Stop use and ask a doctor if

- Rash, itching, or excessive skin irritation develops
- conditions worsen
- symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days

If pregnant or breas-feeding

- ask a health professional before use.

Keep out of reach of children

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

Directions

Adults and children over 12 years of age

- clean and dry affected area
- remove patch from film
- remove patch slowly and gentle from the skin after at most 8 hours application

Children under 12 years of age:

consult a doctor

Inactive ingredients

Zinc oxide, Polybutene

Ageranium Patch

AGERANIUM PATCH

capsaicin patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71955-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.228 mg in 99.13 mg

Inactive Ingredients	
Ingredient Name	**Strength**
POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)	

ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71955-100-02	8 in 1 BOX	12/29/2017	
1	NDC:71955-100-01	4 in 1 POUCH		
1	NDC:71955-100-00	99.13 mg 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	12/29/2017	

Labeler - Entom Co., Ltd. (690106385)

Registrant - Lanec Inc. (052790515)

Establishment

Name	Address	ID/FEI	Business Operations
Entom Co., Ltd.		690106385	manufacture(71955-100)

Revised: 12/2017 Entom Co., Ltd.