

ROSE SAP PATCH - topical starch poultice
KJI Industrial 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.

Warnings: For external use only

Do Not Use

- on wounds, damaged skin or face
- if you are allergic to any ingredients of this product
- with or at the same time as other external product

When using this product

- do not use otherwise than directed
- do not stretch out the adhesive tape
- do not take out the contents from the patch
- if patch is ripped, discard immediately

Stop use and ask a doctor if

- if allergic reaction or irritation occurs
- if you are pregnant, nursing or under medical treatment

Keep out of reach of children

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

Directions

Adults and children 4 years of age and over:

Step 1: Clean and dry area for the patch to be attached

Step 2: Remove the protective cover sheet and gently apply

Step 3: Leave it on at least 4 hours before removal

Children under 4 years of age: Consult a doctor

Storage

- Avoid storing product in direct sunlight
- Keep it in a dry and cool place

Active Ingredient:

Topical Starch 73% Skin Protectant

Inactive Ingredients:

Wood Vinegar, Tourmaline, Agaricus, Eucalyptus oil, Mugwort extract, Loquat extract, Vitamin C, Chitosan, Highly purified Silica, Pearlstone, Polyhydric alcohol, Rose oil

14 patches size(mm):160X125X40



ROSE SAP PATCH

topical starch poultice

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:34690-5001 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| STARCH, CORN (UNII: O8232NY3SJ) (STARCH, CORN - UNII:O8232NY3SJ) | STARCH, CORN | 2.92 g in 4 g |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:34690-5001-2 | 4 g in 1 BOX | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part347 | 01/15/2010 | |

Labeler - KJI Industrial Co Ltd (688453179)

Registrant - KJI Industrial Co Ltd (688453179)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------|---------|-----------|---------------------|
| KJI Industrial Co Ltd | | 688453179 | manufacture |

Revised: 1/2010

KJI Industrial Co Ltd