CAPSAICIN- capsaicin patch
FORREAL PHARMACEUTICALS LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Capsaicin Patch

CAPSAICIN – Capsaicin 0.025% Patch

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.

Capsaicin 0.025% Patch

Drug Facts

Active ingredient

Capsaicin 0.025%

Purpose

External analgesic

Uses

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

- arthritis
- simple backache
- strains
- bruises
- sprains

Warnings

For external use only. Use only as directed or as directed by a health care professional

Read all warnings and directions before use.

Discontinue use at least one hour prior to bath, shower, or swimming; do not use

immediately after bath, shower, or swimming.

Do not use

• On wounds, cuts, damaged or infected skin

• On eyes, mouth, genitals, or any other mucous membranes

Allergy Alert: if you are allergic to capsicum or chili peppers or any inactive ingredient of this product, contact a doctor before use.

When using this product

• You may experience a burning sensation. The intensity of this reaction varies among individuals and may be severe. With regular use, this sensation generally disappears after several days.

• Avoid contact with the eyes, lips, nose and mucous membranes

• Do not tightly wrap or bandage the treated area

• Do not apply heat to the treated area immediately before or after use

Stop use and ask a physician:

• If pregnant or breast feeding

• If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a physician.

• If severe burning persists or blistering occurs

Keep out of reach of children and pets.

If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

Adults and children 18 years of age and older:

Apply 1 patch to the affected area of intact skin up to 3 times a day. Do not leave patch on for more than 8 hours at a time.

- Clean and dry the affected area.
- Open pouch and remove one patch.
- Remove any protective film and apply directly to affected area of pain. Apply immediately after removal from the protective envelope.
- Wash hands with soap and water after handling the patches.
- Reseal pouch containing unused patches after each use. Do not store patch outside the sealed envelope.
- Fold used patches so that the adhesive side sticks to itself and safely discard used patches or pieces of cut patches where children and pets cannot get to them.

Children under 18 years: Ask a physician

Other information

Store at room temperature 15°-30°C (59°-86°F)

Inactive ingredients

Glycerin, Sodium polyacrylate, Dihydroxyaluminum aminoacetate, Edetate disodium, Kaolin, Carboxymethylcellulose sodium, Titanium dioxide, L-Tartaric acid, Polyacrylic acid, Capsaicin, Propylene glycol, Polysorbate 80, Petrolatum, Hydroxyacetophenone, Water, PVP

PRINCIPAL DISPLAY PANEL

NDC 81877-515-15

Qty: 15 Patches
(5 per Resealable Pouch) x 3

Capsaicin 0.025%
Topical Pain Patch
for temporary pain relief

Forreal Pharmaceuticals LLC

CAPSAICIN
capsaicin patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81877-515
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.025 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
KAOLIN (UNII: 24H4NWX5CO)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TARTARIC ACID (UNII: W4888I119H)	
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PETROLATUM (UNII: 4T6H12BN9U)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:81877-515-15	15 in 1 CARTON	08/16/2022	
1		100 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
unapproved drug other		08/16/2022	

Labeler - FORREAL PHARMACEUTICALS LLC (118029197)

Revised: 8/2022 FORREAL PHARMACEUTICALS LLC