NYLOXIN STAGE 2 PAIN RELIEF- naja naja venom gel
RECEPTOPHARM INC

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

DRUG FACTS

Active Ingredients

Asian Cobra venom 5X

Purpose

Analgesic*

* According to the Homeopathic Pharmacopeia of the United States

Uses: Temporarily relieves joint pain associated with overuse and pain associated with arthritis.

Warnings:

- For external use only
- If symptoms persist or worsen, discontinue use and seek medical attention.
- Avoid contact with eyes. If product gets into eyes, flush with water. Seek medical attention.
- Not for use on open wounds.

Directions For Use:

- Remove protective wrapping.
- Liberally apply gel to the affected area and rub into joints.
- Use 3-4 times per day for the first week. Use as needed thereafter to relieve discomfort.
- Allow several days for drug to take maximum effect.

Other Information:

- Do not use if container seal is broken prior to opening.
- This product is intended for use in cases of recurring joint pain.
- This product is NOT intended to treat disease. It provides a temporary level of comfort, relief and a feeling of wellness.
- This product has been determined to be safe and effective for mild to moderate (Stage 2) chronic pain, as indicated by the Homeopathic Pharmacopea of the United States.

- **Pregnant or nursing women and children should not use this product unless advised by a physician**

Inactive Ingredients:

Benzalkonium chloride, Ethanol, Methocel, Propylene glycol, Saline

Package Label - Principal Display Panel – 2.0 oz Gel Label

Package Label - Principal Display Panel – 2.0 oz Gel Carton

NYLOXIN STAGE 2 PAIN RELIEF

naja naja venom gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:47219-204
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
NAJA NAJA VENOM (UNII: ZZ4AG7L7VM) (NAJA NAJA VENOM - UNII:ZZ4AG7L7VM)	NAJA NAJA VENOM	.020 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	

2-(DIETHYLAMINO)ETHANOL (UNII: S6DL4M053U)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47219-204-20	1 in 1 BOX		
1		30 mL in 1 BOTTLE, DISPENSING		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved homeopathic		08/25/2009	

Labeler - RECEPTOPHARM INC (145377888)

Establishment

Name	Address	ID/FEI	Business Operations
RECEPTOPHARM INC		145377888	ANALYSIS, MANUFACTURE, API MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
LIQUID PACKAGING RESOURCES		018935165	MANUFACTURE

Revised: 11/2009 RECEPTOPHARM INC