NYLOXIN STAGE 2 PAIN RELIEF- naja naja venom spray, metered 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 3.8X

Purpose

Analgesic*

Uses: Temporarily relieves pain associated with sore back, inflamed joints, migraines, painful menses, and general persistent pain

Warnings:

- Side effects may include headahce, nausea, sore throat, allergic rhinitis and gastointestinal upset.
- If symptoms persist or worsen, stop using this product and consult a physician.
- When Using This Product: avoid contact with the eyes. If product gets into eyes, flush with water. Seek medical attention.

Directions For Use:

- Break off protective tab.
- Turn press lock so spray nozzle is visible in front.
- Press down 4 x to prime the pump.
- Spray 2 x directly into mouth or under tongue.
- Use spray initially every 3-4 hours.

Other Information:

- Do not use if tamper-proof seal is broken.
- This product is NOT intended to treat disease, it can provide a temporary level of comfort, relief and a feeling of wellness.
- This product has been determined to be safe and effective for moderate to severe (Stage 2) pain.
- Clinical experience suggests Nyloxin may provide relief from other forms of pain.
- Pregnant or nursing women and children should not use this product unless advised by a physician.

Inactive Ingredients:

Citric Acid, Ethanol, Flavoring, Methylparaben, Sodium Citrate, Xylitol.

Package Label - Principal Display Panel - 1.0 oz Spray Label

^{*} According to the Homeopathic Pharmacopeia of the United States



Package Label - Principal Display Panel - 1.0 oz Spray Carton



NYLOXIN STAGE 2 PAIN RELIEF

naja naja venom spray, metered

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:47219-201	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
NAJA NAJA VENOM (UNII: ZZ4AG7L7VM) (NAJA NAJA VENOM - UNII:ZZ4AG7L7VM)	NAJA NAJA VENOM	.070 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		

ANHYDROUS TRISODIUM CITRATE (UNII: RS7A450 LGA)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
XYLITOL (UNII: VCQ006KQ1E)	
2-(DIETHYLAMINO)ETHANOL (UNII: S6DL4M053U)	

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:47219-201-10	1 in 1 BOX			
1	30 mL in 1 BOTTLE, SPRAY			

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

Labeler - RECEPTO PHARM INC (145377888)

Establishment			
Name	Address	ID/FEI	Business Operations
RECEPTO PHARM INC		145377888	ANALYSIS, MANUFACTURE, API MANUFACTURE

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

Revised: 11/2009 RECEPTOPHARM INC