NYLOXIN STAGE 3 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 350 mcg/mL

Purpose

Analgesic*

* According to the Homeopathic Pharmacopeia of the United States

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

Package Label - Principal Display Panel – 1.0 oz Spray Carton

NYLOXIN STAGE 3 PAIN RELIEF

naja naja venom spray, metered

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:47219-252
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	350 ug in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

ANHYDROUS TRISODIUM CITRATE (UNII: RS7A450LGA)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
XYLITOL (UNII: VCQ006KQ1E)	
2-(DIETHYLAMINO)ETHANOL (UNII: S6DL4M053U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47219-252-10	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 - 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