PROTOXIN- clostridium botulinum toxin type a gel
PROTOX Inc.

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.

Clostridium botulinum Toxin Type A

Normal human serum albumin, Sodium chloride

Stop a secretion of the neurotransmitter acetylcholine in a place to see nerves and muscles.
Lessening the rigidity of the child with cerebral palsy using the qualities that lead to muscle paralysis.

Keep out of reach of children.

Confirm the validity of the product label

to make sure the sterilizatios is not damaged before using

N/A

N/A

CONTENT OF LABELING

- [OTC - ACTIVE INGREDIENT SECTION]

Clostridium botulinum Toxin Type A

- [INACTIVE INGREDIENT SECTION]

Normal human serum albumin, Sodium chloride

- [OTC - PURPOSE SECTION]

Stop a secretion of the neurotransmitter acetylcholine in a place to see nerves and muscles.
Lessening the rigidity of the child with cerebral palsy using the qualities that lead to muscle paralysis.

- [OTC - KEEP OUT OF REACH OF CHILDREN SECTION]

Keep out of reach of children.

- [INDICATIONS & USAGE SECTION]

Dilution with saline solution

direct injection to the affected area

- [WARNINGS SECTION]

Confirm the validity of the product label

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- [DOSAGE & ADMINISTRATION SECTION]

N/A

- [PACKAGE LABEL.PRINCIPAL DISPLAY PANEL]

undefined

PROTOXIN

clostridium botulinum toxin type a gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71066-0001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CLOSTRIDIUM BOTULINUM (UNII: 0296055VE0) (CLOSTRIDIUM BOTULINUM - UNII:0296055VE0)	CLOSTRIDIUM BOTULINUM	10 g in 10 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALBUMIN HUMAN (UNII: ZIF514RVZR)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:71066-0001-1	10 mL in 1 VIAL; Type 0: Not a Combination Product	11/10/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/10/2016	

Labeler - PROTOX Inc. (689846300)

Registrant - PROTOX Inc. (689846300)

Establishment

Name	Address	ID/FEI	Business Operations
PROTOX Inc.		689846300	manufacture(71066-0001)

Revised: 11/2016 PROTOX Inc.