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.

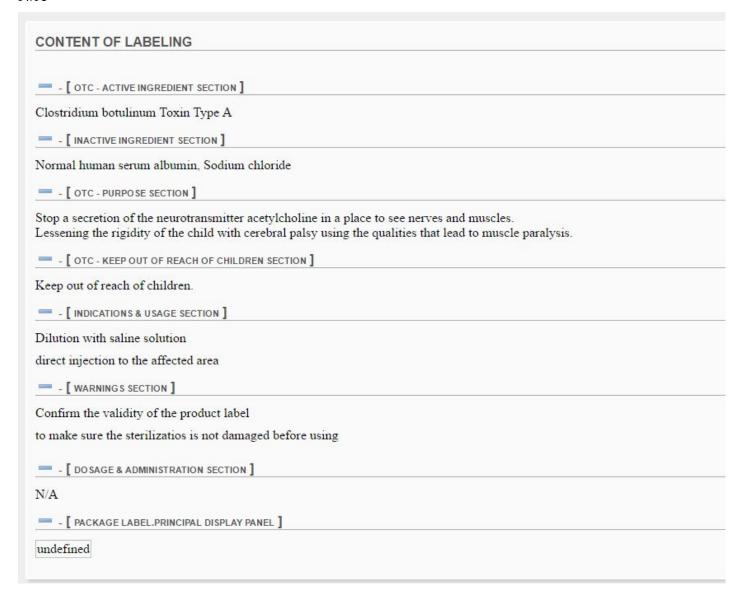
Keep out of reach of children.

Confirm the validity of the product label

to make sure the sterilizatios is not damaged before using

N/A

N/A



PROTOXIN

clostridium botulinum toxin type a gel

| Drod | net | Info | rmation | |
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Route of Administration TOPICAL

Active Ingredient/Active Moiety

| ı | reave ingredient reave projecty | | |
|---|---|--------------------------|------------------|
| ı | Ingredient Name | Basis of Strength | Strength |
| | CLOSTRIDIUM BOTULINUM (UNII: 0296055VE0) (CLOSTRIDIUM BOTULINUM - UNII:0296055VE0) | CLOSTRIDIUM BOTULINUM | 10 g in 10 mL |

Inactive Ingredients

| imetive ingredients | | | |
|------------------------------------|----------|--|--|
| Ingredient Name | Strength | | |
| ALBUMIN HUMAN (UNII: ZIF514RVZR) | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | |

Packaging

| ı | - ucimging | | | | |
|---|---------------------------------|-----------------|--|---------------------------|--|
| ı | # Item Code Package Description | | Marketing Start Date | Marketing End Date | |
| ı | 1 N | DC: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.