PRO PH FILLER- hyaluronic acid 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.

crosslinked hyaluronic acid dermal filler

PLLA, Lidocaine

n/a

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]
crosslinked hyaluronic acid dermal filler
- [INACTIVE INGREDIENT SECTION]
PLLA, Lidocaine
- [OTC - PURPOSE SECTION]
n/a
- [OTC - KEEP OUT OF REACH OF CHILDREN SECTION]
Keep out of reach of children.
- [WARNINGS SECTION]
Confirm the validity of the product label
to make sure the sterilizatios is not damaged before using
- [DOSAGE & ADMINISTRATION SECTION]
N/A
- [INDICATIONS & USAGE SECTION]
N/A
- [PACKAGE LABEL.PRINCIPAL DISPLAY PANEL]

PRO PH FILLER

hyaluronic acid gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71066-0002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
HYALURO NIC ACID (UNII: S270 N0 TRQY) (HYALURO NIC ACID - UNII: S270 N0 TRQY)	HYALURONIC ACID	1000 g in 20 mL	

Inactive Ingredients			
Ingredient Name	Strength		
LIDO CAINE (UNII: 98PI200987)			
LACTIC ACID (UNII: 33X04XA5AT)			

Packaging				
# Item Code Package Description		Marketing Start Date	Marketing End Date	
ı	1 NDC:71066-0002-1	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(71066-0002)	

Revised: 11/2016 PROTOX Inc.