NATURES TEARS- natures tears solution/ drops Rebel Distributors Corp

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Nature's Tears Drug Facts

Active ingredient

Hypromellose

Purpose

Lubricant

Keep Out of Reach of Children

If swallowed, get medical help or contact a Poison Control Center right away.

Uses

° relieves dryness of the eye

° prevents further irritation

Warnings

Do not use if solution changes color or becomes cloudy

When using this product:

° do not touch tip of container to any surface to avoid contamination

° replace cap after use

Stop use and ask a doctor if:

° you experience eye pain, changes in vision, continued redness or irritation of the eye

° condition worsens or persists for more than 72 hours

Directions

° instill 1 or 2 drops in the affected eye(s) as needed

Other Information

° store at 15° - 30°C (59° - 85°F)

° keep tightly closed

FOR USE IN THE EYES ONLY

Inactive ingredients

dibasic sodium phosphate, edetate disodium, monobasic sodium phosphate,

potassium chloride, sodium chloride, purified water. Hydrochloric acid and/or sodium hydroxide may be added to adjust pH. Preservative added: benzalkonium chloride 0.01%

Questions of Comments?

Call 1-800-645-2158

9 am - 5 pm ET, Monday-Friday.

Serious side effects associated with use of this product may be reported to this number.

Distributed by:

Rugby Laboratories, Inc.

Duluth, GA 30097

Repackaged by:

Rebel Distributors Corp.

Thousand Oaks, CA 91320

Package/Label Principal Display Panel



NATURES TEARS									
natures tears solution/ drops									
-									
Product Information									
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21695-930(NDC:0536-6237)						
Route of Administration	OPHTHALMIC								
Active Ingredient/Active Moiety									
Ing	Basis of Strength	Strength							
HYPROMELLOSE 2910 (3 MPA.S) (UNII: 0 VUT3PMY82) (HYPROMELLOSES - UNII:3NXW29 V3WO)			HYPROMELLOSE 2910 (3 MPA.S)	4 mg in 1 mL					

Inactive Ingredients									
Ingredient Name						Strength			
s	SO DIUM PHO SPHATE, DIBASIC (UNII: GR686LBA74)								
El	EDETATE DISO DIUM (UNII: 7FLD91C86K)								
S	SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)								
P	POTASSIUM CHLORIDE (UNII: 660 YQ98 I10)								
s	SODIUM CHLORIDE (UNII: 451W47IQ8X)								
W	ATER (UNII: 059QF0K	00R)							
B	BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7)								
Packaging									
#	Item Code	Package Description	Marketing Start Date		Mar	Marketing End Date			
1	NDC:21695-930-15	15 mL in 1 BOTTLE							
Marketing Information									
N	Aarketing Category	Application Number or Monograph Citation		Marketing Start Date		Marketing End Date			
0	TC monograph final	part349		03/29/2011					

Labeler - Rebel Distributors Corp (118802834)

Establishment									
Name	Address	ID/FEI	Business Operations						
Rebel Distributors Corp		118802834	RELABEL, REPACK						

Revised: 4/2011

Rebel Distributors Corp