MINERAL OIL- lacri-lube ointment
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.

Lacri-Lube Drug Facts

Active ingredient

Mineral Oil 42.5%

White Petrolatum 56.8%

Purpose

Eye lubricant

Keep Out of Reach of Children

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

Uses

For use as a protectant against further irritation or to relieve dryness or the eye.

Warnings

For external use only.

To avoid contamination, do not touch tip of container to any surface.

Replace cap after using.

Stop use and ask a doctor if you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours.

Directions

Pull down the lower lid of the affected eye and apply a small amount (one-fourth inch) of ointment to the inside of the eyelid.

Other Information

Use only if imprinted tape seals on top and bottom flaps are intact and clearly legible.

Store away from heat. Protect from freezing.

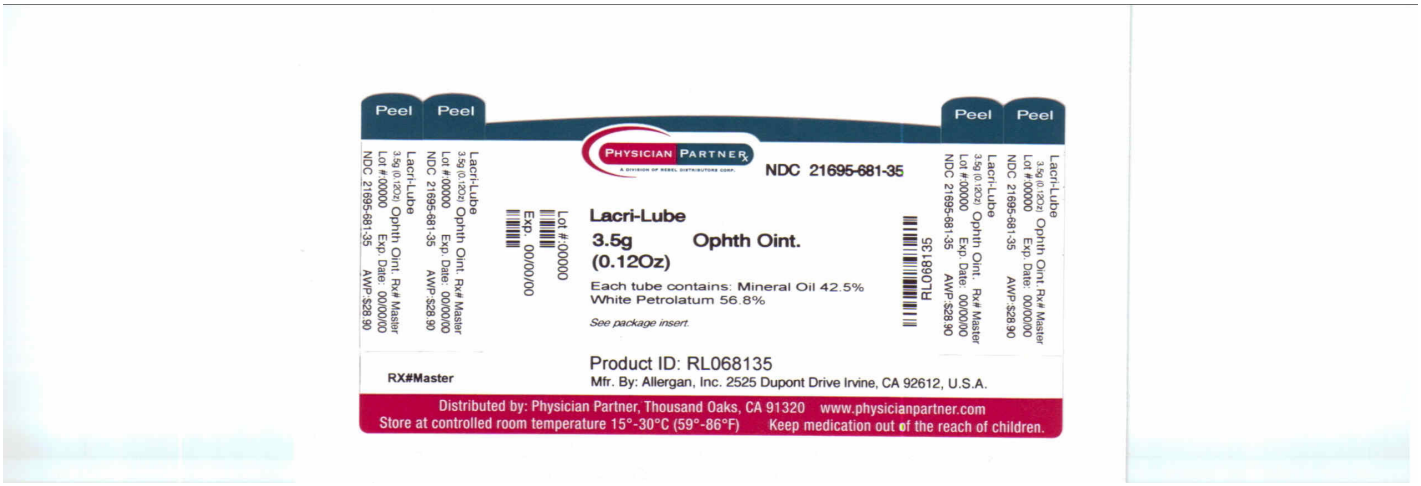
Use before expiration date marked on container.

RETAIN THIS CARTON FOR FUTURE REFERENCE.

Inactive ingredients

Chlorobutanol and lanolin alcohols.

Package/Label Principal Display Panel



MINERAL OIL

lacri-lube ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:21695-681(NDC:0023-0312)
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	425 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	568 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
CHLOROBUTANOL (UNII: HM4YQM8WRC)	
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:21695-681-35	3.5 g in 1 TUBE		
2	NDC:21695-681-07	7 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	11/30/2007	

Labeler - Rebel Distributors Corp (118802834)

Establishment

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

Revised: 2/2011 Rebel Distributors Corp