

**ARTIFICIAL TEARS- white petrolatum mineral oil ointment**  
**Rugby Laboratories Inc.**

*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.*

-----

**Artificial Tears Ointment Drug Facts**

**Active ingredient**

Mineral oil 15%  
White petrolatum 83%

**Purpose**

Lubricant

**Uses**

- prevents further irritation
- relieves dryness of the eye

**Warnings**

**When using this product**

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

**Stop use and ask a doctor if**

- condition worsens or persists for more than 72 hours
- you experience eye pain, changes in vision, continued redness or irritation of the eye

**Keep out of reach of children.**

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

**Directions**

pull down the lower lid of the affected eye (s)  
apply a small amount (1/4 inch) of ointment to the inside of eyelid

**Other information**

- store at 15° - 30°C (59° - 86°F)
- keep tightly closed
- replace cap after use
- see crimp of tube or carton for Lot Number and Expiration Date

**Inactive ingredient**

lanolin oil

## Questions or 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.

## Package/Label Principal Display Panel



NDC 0536-6550-91

Rugby®

STERILE

Artificial Tears Ointment

Lubricant Ophthalmic Ointment

PRESERVATIVE FREE

Prevents irritation and relieves dryness of the eye

Rugby®

Net Wt. 1/8 oz (3.5 g)

## ARTIFICIAL TEARS

white petrolatum mineral oil ointment

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:0536-6550 |
| <b>Route of Administration</b> | OPHTHALMIC     |                           |               |

### Active Ingredient/Active Moiety

| <b>Ingredient Name</b>   | <b>Basis of Strength</b> | <b>Strength</b> |
|--|--------------------------|-----------------|
| MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP) | MINERAL OIL              | 150 mg in 1 g   |
| PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)   | PETROLATUM               | 830 mg in 1 g   |

### Inactive Ingredients

| <b>Ingredient Name</b>     | <b>Strength</b> |
|----------------------------|-----------------|
| LANOLIN (UNII: 7EV65EAW6H) |                 |

### Packaging

| <b>#</b> | <b>Item Code</b> | <b>Package Description</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|----------|------------------|----------------------------|-----------------------------|---------------------------|
| 1        | NDC:0536-6550-91 | 3.5 g in 1 TUBE            |                             |                           |

### Marketing Information

| <b>Marketing Category</b> | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph final       | part349   | 10/07/2011                  |                           |

**Labeler** - Rugby Laboratories Inc. (109178264)

**Registrant** - Bausch & Lomb Incorporated (196603781)

### Establishment

| <b>Name</b>                | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
|----------------------------|----------------|---------------|----------------------------|
| Bausch & Lomb Incorporated |                | 196603781     | MANUFACTURE                |

Revised: 11/2011

Rugby Laboratories Inc.