

**AVITEARS- polysorbate 80 solution/ drops**  
**Pinnacle Science, LLC**

*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.*

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**Avitears Lubricating Eye Drops**

**Drug Facts**

**Active Ingredient**

Polysorbate 80, 1%

**Purpose**

Lubricant

**Uses**

- Temporary relief of discomfort, burning and irritation due to dryness of the eye or from exposure to wind, sun, computer use, environmental conditions, prescription medication, post-surgical dry eye or systemically induced dry eye.
- Lubricant and protectant from further irritation

**Warnings**

- For external use only
- To avoid contamination replace cap after use
- Do not touch the tip of the container to any surface to avoid contamination
- Do not use if solution changes color or becomes cloudy

**Stop use and ask a doctor**

- If you experience eye pain, changes in vision, continued redness or irritation, or if condition persists for more than 72 hours or worsens
- Keep this and all other drugs out of the reach of children

**Directions**

- Instill one or two drops in the affected eye(s) as needed

**Other Information**

Store at 20 to 25° C (68 to 77° F)

Controlled USP Room Temperature

**Inactive Ingredients**

Citric acid, edetate disodium, WFI water, sodium chloride and the antioxidants: mannitol, pyruvate, retinyl palmitate and sodium citrate.

## Principal Display Panel 10mL Bottle Label

Avitears™

Lubrication Eye Drops

**0.33 FL.OZ**

**(10mL)**

**Maximum Strength for Dry Eyes**



## Principal Display Panel 10mL Carton Label

Sterile

Avitears™

Lubrication Eye Drops

**.33 FL.OZ**

**(10mL)**

**No Preservatives**

**Antioxidant Based**

**Maximum Strength for Dry Eyes**



## Principal Display Panel 15mL Bottle Label

Avitears™

Lubrication Eye Drops

**0.5 FL.OZ**

**(15mL)**

**Maximum Strength for Dry Eyes**



**Principal Display Panel 15mL Carton Label**

Sterile

Avitears™

Lubrication Eye Drops

.5 FL.OZ

(15mL)

No Preservatives

Antioxidant Based

Maximum Strength for Dry Eyes



**AVITEARS**

polysorbate 80 solution/ drops

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49869-002
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
polysorbate 80 (UNII: 6OZP39ZG8H) (polysorbate 80 - UNII:6OZP39ZG8H)	polysorbate 80	10 mg in 1 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
sodium citrate (UNII: 1Q73Q2JULR)	
sodium chloride (UNII: 451W47IQ8X)	
citric acid monohydrate (UNII: 2968PHW8QP)	
mannitol (UNII: 3OWL53L36A)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:49869-002-02	10 mL in 1 BOTTLE, PLASTIC		
2	NDC:49869-002-01	15 mL in 1 BOTTLE, PLASTIC		

**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	07/17/2009	

**Labeler** - Pinnacle Science, LLc (828202494)

Revised: 8/2009

Pinnacle Science, LLc