

**INDOCO REMEDIES LTD. Packaging Development Department**

|               |                                     |
|---------------|-------------------------------------|
| Item:         | <b>Leaflet</b>                      |
| Item Code:    | P2YB00003                           |
| Open Size:    | 130 x 300 mm                        |
| Folding Size: | H:Unfolded: 300 mm    Folded: 23 mm |
|               | W:Unfolded:130 mm                   |
| GSM/ Paper:   | 54 gsm Maplitho Paper               |
| Colour:       | Black                               |
| Pharmacode:   | 65 mini                             |
| Layout No.:   |                                     |

**Reason for Preparation/ Revision:**

1) New Development

|             |            |             |
|-------------|------------|-------------|
| Prepared by | Checked by | Approved by |
|             |            |             |

Path

Y:\Art-work\K\Ketotifen Fumarate\BAYSHORE PHARM\Current\Ketotifen Bayshore Pharma 5 ml Leaflet P2YB00003.cdr

R1

**Date: 07.08.2020 / 20.08.2020**

|  |   |
|--|---|
| <p><b>Front</b></p> <p style="text-align: center;">130 mm</p> <div style="border: 1px solid black; padding: 10px;"> <p align="center"><b>KETOTIFEN FUMARATE- ketotifen fumarate solution / drops</b></p> <p><b>Drug Facts</b></p> <p><b>Active Ingredients Purpose</b><br/>Ketotifen (0.025%) Antihistamine<br/>(equivalent to ketotifen fumarate 0.035%)</p> <p><b>Inactive ingredients</b><br/>benzalkonium chloride 0.01%, glycerol, water for injection, sodium hydroxide and/or hydrochloric acid.</p> <p><b>Use</b><br/>Temporarily relieves itchy eyes due to pollen, ragweed, grass, animal hair and dander.</p> <p><b>Warnings</b><br/>For External Use Only</p> <p><b>Do not use</b><br/>if solution changes color or becomes cloudy<br/>if you are sensitive to any ingredient in this product<br/>to treat contact lens related irritation</p> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>• do not touch tip of container to any surface to avoid contamination</li> <li>• remove contact lenses before use</li> <li>• wait at least 10 minutes before reinserting contact lenses after use</li> <li>• replace cap after each use</li> </ul> <p><b>Stop use and ask doctor if you experience any of the following:</b></p> <ul style="list-style-type: none"> <li>• eye pain</li> <li>• changes in vision</li> <li>• redness of the eye</li> <li>• itching worsens or lasts for more than 72 hours</li> </ul> <p><b>Keep out of reach of children.</b><br/>If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <p><b>Adults and children 3 years and older:</b><br/>Put 1 drop in the affected eye(s) twice daily, every 8 to 12 hours, no more than twice per day.</p> <p><b>Children under 3 years of age:</b> Consult a doctor.</p> <p><b>Other Information</b></p> <ul style="list-style-type: none"> <li>• Only for use in the eye.</li> <li>• Store between 20° to 25°C (68° to 77°F).(See USP Controlled Room Temperature)</li> </ul> <p><b>Questions?</b><br/>Call Product Information at 1-973-218-2683. Serious side effects associated with use of this product may be reported to this number.</p> <p><b>Product Information</b><br/><b>Product Type :</b> HUMAN OTC DRUG<br/><b>Item Code (Source):</b> NDC 76385-106-17<br/><b>Route of Administration:</b> OPHTHALMIC<br/><b>Package Description:</b> 5mL in 1 BOTTLE, DROPPER (5mL (0.17 FLOZ) Sterile<br/><b>TEAR AND DISCARD RING BEFORE USE</b></p> <p><b>Manufactured For</b><br/>Bayshore Pharmaceuticals LLC,<br/>Short Hills, NJ 07078</p> <p><b>Issued : Dec 2019</b></p> <p><b>Made in India</b></p> <p align="right">P2YB00003</p> </div> | <p><b>Back</b></p> <p style="text-align: center;">130 mm</p> <div style="border: 1px solid black; height: 600px; width: 100%;"></div> |
|--|---|

10 mm

7.5 mm

70 mm