## EDA Home<sup>3</sup> Drug Databases<sup>4</sup> Orange Book<sup>5</sup> Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations Search results from the "OB\_Rx" table for query on "021862."

| Active Ingredient:                           | NEPAFENAC                   |
|--|-----------------------------|
| Dosage Form;Route:                           | SUSPENSION/DROPS;OPHTHALMIC |
| Proprietary Name:                            | NEVANAC                     |
| Applicant:                                   | ALCON PHARMS LTD            |
| Strength:                                    | 0.1%                        |
| Application Number:                          | N021862                     |
| Product Number:                              | 001                         |
| Approval Date:                               | Aug 19, 2005                |
| Reference Listed Drug                        | Yes                         |
| RX/OTC/DISCN:                                | RX                          |
| TE Code:                                     |                             |
| Patent and Exclusivity Info for this product | : View                      |

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#### Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations Patent and Exclusivity Search Results from query on Appl No 021662 Product 001 in the OB\_RX list.

## Patent Data

| Appl No | Prod No | Patent No | Patent<br>Expiration | Drug Substance<br>Claim | Drug Product<br>Claim | Patent Use<br>Code | Delist<br>Requested |
|---------|---------|-----------|----------------------|-------------------------|-----------------------|--------------------|---------------------|
| N021862 | 001     | 7834059   | Jan 31, 2027         |                         |                       | U - 1095           |                     |
| N021862 | 001     | 8071648   | Dec 2, 2025          |                         | Y                     |                    |                     |
| N021862 | 001     | 8324281   | Dec 2, 2025          |                         | Y                     |                    |                     |

### **Exclusivity Data**

There is no unexpired exclusivity for this product.

### Additional information:

- 1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).
- 2. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. These patents may not be flagged with respect to other claims which may apply.

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|---|
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