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New Drug Application (NDA): 022260

Company: ACTELION PHARMS LTD

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Products on NDA 022260



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| Drug Name | Active Ingredients | Strength | Dosage Form/Route | Marketing Status | RLD | TE Code |
|-----------|---------------------|--------------------|----------------------|------------------|-----|---------|
| VELETRI | EPOPROSTENOL SODIUM | EQ 1.5MG BASE/VIAL | INJECTABLE;INJECTION | Prescription | Yes | None |
| VELETRI | EPOPROSTENOL SODIUM | EQ 0.5MG BASE/VIAL | INJECTABLE;INJECTION | Prescription | Yes | None |

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 022260



Original Approvals or Tentative Approvals

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| Action Date | Submission | Action Type | Submission Classification | Review Priority; Orphan Status | Letters, Reviews |
|-------------|------------|-------------|--|--------------------------------|---|
| 06/27/2008 | ORIG-1 | Approval | Type 5 - New Formulation or New Manufacturer | STANDARD | Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2008/012511Orig1s01.pdf) Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2008/012511Orig1s01.pdf) Summary Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2008/012511Orig1s01.pdf) |

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Supplements

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| Action Date | Submission | Submission Classification | Letters, Reviews, Labels, Patient Package Insert |
|-------------|------------|---|---|
| 07/18/2016 | SUPPL-8 | Manufacturing (CMC) | |
| 03/03/2015 | SUPPL-7 | Manufacturing (CMC) | |
| 06/28/2012 | SUPPL-5 | Manufacturing (CMC) | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022260s01.pdf) |
| 03/30/2011 | SUPPL-4 | Labeling- Package Insert | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022260s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2011/022260s01.pdf) |
| 08/23/2010 | SUPPL-2 | Labeling- Proprietary Name Change | Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022260s01.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2010/022260s01.pdf) |

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Labels for NDA 022260

