# Drugs@FDA: FDA Approved Drug Products



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**New Drug Application (NDA):** 022260
**Company:** ACTELION PHARMS LTD



## 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/ Review (https://www.accessdata.fda.gov/drug Summary Review (PDF) (https://www.accessd** |

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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/2012/022260s0** |
| 03/30/2011 | SUPPL-4 | Labeling-Package Insert | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022260s0 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/02226** |
| 08/23/2010 | SUPPL-2 | Labeling-Proprietary Name Change | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022260s0 Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/02226** |

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**Labels for NDA 022260**