# ıgs@FDA: FDA Approved ıg Products



ndex.cfm) | Previous Page

**g Application (NDA):** 020353
**y:** ALVOGEN MALTA



ation Guide
'/www.fda.gov/downloads/Drugs/DrugSafety/UCM280324.pdf)

cts on NDA 020353

/ Excel Print

| g ne | Active Ingredients | Strength | Dosage Form/Route | Marketing Status | TE Code |
|---|---|---|---|---|---|
| ELAN | NAPROXEN SODIUM | EQ 375MG BASE | TABLET, EXTENDED RELEASE;ORAL | Prescription | AB |
| ELAN | NAPROXEN SODIUM | EQ 500MG BASE | TABLET, EXTENDED RELEASE;ORAL | Prescription | AB |
| ELAN | NAPROXEN SODIUM | EQ 750MG BASE | TABLET, EXTENDED RELEASE;ORAL | Prescription | AB |

ng 1 to 3 of 3 entries

val Date(s) and History, Letters, Labels, Reviews for NDA 020353

al Approvals or Tentative Approvals

/ Excel Print

| on e | Submission | Action Type | Submission Classification | Review Priority; Orphan Status | Letters, Reviews, Labels, Patient Package Insert |
|---|---|---|---|---|---|
| 1996 | ORIG-1 | Approval | Type 3 - New Dosage Form | STANDARD | |

ng 1 to 1 of 1 entries

ements

/ Excel Print

| on e | Submission | Supplement Categories or Approval Type | Letters, Reviews, Labels, Patient Packa |
|---|---|---|---|
| 2017 | SUPPL-34 | Manufacturing (CMC)-Facility | **Label (PDF) (https://www.accessdata.fda.gov/** |
| 2016 | SUPPL-32 | Labeling-Package Insert | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_ Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_** |
| 2016 | SUPPL-31 | Labeling-Medication Guide, Labeling-Package Insert | **Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_ Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_** |
| 2014 | SUPPL-30 | Manufacturing (CMC) | |
| 2011 | SUPPL-28 | Labeling-Package Insert | **Label (PDF) (https://www.accessdata.fda.gov/ Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_** |
| 2009 | SUPPL-23 | Labeling-Container/Carton Labels, Labeling-Package Insert | **Label (PDF) (https://www.accessdata.fda.gov/ Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_** |
| 2007 | SUPPL-19 | Labeling | **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_** |
| 2006 | SUPPL-16 | Labeling | **Label (PDF) (https://www.accessdata.fda.gov/ Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_** |
| 2002 | SUPPL-14 | Manufacturing (CMC)-Control | |

| on e | Submission | Supplement Categories or Approval Type | Letters, Reviews, Labels, Patient Packa |
|---|---|---|---|
| 2002 | SUPPL-8 | Labeling | |
| 2001 | SUPPL-13 | Manufacturing (CMC) | |
| 2001 | SUPPL-12 | Manufacturing (CMC)-Packaging | |
| 2000 | SUPPL-11 | Manufacturing (CMC)-Control | |
| 2000 | SUPPL-10 | Manufacturing (CMC)-Packaging | |
| 1999 | SUPPL-7 | Manufacturing (CMC)-Control | |
| 1999 | SUPPL-9 | Manufacturing (CMC)-Packaging | |
| 1997 | SUPPL-6 | Manufacturing (CMC)-Packaging | |

| on e | Submission | Supplement Categories or Approval Type | Letters, Reviews, Labels, Patient Packa |
|---|---|---|---|
| 1997 | SUPPL-5 | Manufacturing (CMC)-Expiration Date | |
| 1997 | SUPPL-4 | Manufacturing (CMC)-Expiration Date | |
| 1997 | SUPPL-3 | Manufacturing (CMC)-Control | |
| 1996 | SUPPL-1 | Labeling | **Review (https://www.accessdata.fda.gov/drugsatfda_** |

ng 1 to 21 of 21 entries

**s for NDA 020353**

**peutic Equivalents for NDA 020353**