

# Drugs@FDA: FDA Approved Drug Products

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g Application (NDA): 020353  
y: ALVOGEN MALTA

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### [Information Guide](#)

<http://www.fda.gov/downloads/Drugs/DrugSafety/UCM280324.pdf>

[Details on NDA 020353](#)

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|           |                    | Excel         | Print                         |                  |         |  |
|-----------|--------------------|---------------|-------------------------------|------------------|---------|--|
| Drug Name | 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      |  |

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**Approval Date(s) and History, Letters, Labels, Reviews for NDA 020353** ^

**Final Approvals or Tentative Approvals**

|               |            | Excel       | Print                     |                                |  |  |
|---------------|------------|-------------|---------------------------|--------------------------------|--|--|
| Approval Date | 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                       |  |  |

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**Comments**

|  |  |       |       |
|--|--|-------|-------|
|  |  | Excel | Print |
|--|--|-------|-------|

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

| Year | 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 ( <a href="https://www.accessdata.fda.gov/drugsatfda_">https://www.accessdata.fda.gov/drugsatfda_</a> |

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