

ALEVE BACK AND MUSCLE PAIN- naproxen sodium tablet
Bayer HealthCare LLC.

Aleve Back & Muscle Pain UI 1600169

Drug Facts

Active ingredient (in each tablet)

Naproxen sodium 220 mg (naproxen 200 mg)

(NSAID)*

*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - backache
 - muscular aches
 - minor pain of arthritis
 - menstrual cramps
 - headache
 - toothache
 - the common cold
- temporarily reduces fever

Directions

- **do not take more than directed**
- **the smallest effective dose should be used**
- drink a full glass of water with each dose

| | |
|--|---|
| Adults and children 12 years and older | <ul style="list-style-type: none">• take 1 tablets every 8 to 12 hours while symptoms last• for the first dose you may take 2 tablets within the first hour• do not exceed 2 tablets in any 8-to 12-hour period• do not exceed 3 tablets in a 24-hour period |
| Children under 12 years | <ul style="list-style-type: none">• ask a doctor |

Other information

- **each tablet contains:** sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

Questions or comments? 1-800-395-0689 (Mon - Fri 9AM - 5PM EST)

Dist. by :

Bayer Healthcare LLC

Whippany, NJ 07981

In case of overdose, get medical help or contact a Poison Control Center right away.

Package label display



All Day Strong®

Aleve®

Back & Muscle Pain

naproxen sodium tablets, 220 mg (NSAID)

Pain reliever/fever reducer

Bayer

For temporary relief of minor back and muscle aches and pains

ACTUAL SIZE

Strength to Last 12 Hours 24Tablets

ALEVE BACK AND MUSCLE PAIN

naproxen sodium tablet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0280-6092 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ) | NAPROXEN SODIUM | 220 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| POVIDONE (UNII: FZ989GH94E) | |
| FD&C BLUE NO. 2 (UNII: L06K8R7DQK) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | blue | Score | no score |
| Shape | ROUND | Size | 8mm |
| Flavor | | Imprint Code | ALEVE |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0280-6092-24 | 1 in 1 CARTON | 01/26/2018 | |
| 1 | | 24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| 2 | NDC:0280-6092-50 | 1 in 1 CARTON | 01/26/2018 | |

| | | | | |
|----|------------------|--|------------|------------|
| 2 | | 50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| 3 | NDC:0280-6092-10 | 1 in 1 CARTON | 01/26/2018 | 09/30/2023 |
| 3 | | 100 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 4 | NDC:0280-6092-25 | 1 in 1 CARTON | 08/06/2019 | |
| 4 | | 250 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 5 | NDC:0280-6092-02 | 1 in 1 CARTON | 01/26/2018 | |
| 5 | | 130 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 6 | NDC:0280-6092-04 | 1 in 1 CARTON | 01/26/2018 | |
| 6 | | 200 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 7 | NDC:0280-6092-05 | 1 in 1 CARTON | 01/26/2018 | |
| 7 | | 225 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 8 | NDC:0280-6092-06 | 1 in 1 CARTON | 01/26/2018 | 03/31/2022 |
| 8 | | 36 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 9 | NDC:0280-6092-07 | 1 in 1 CARTON | 01/26/2018 | 11/30/2021 |
| 9 | | 65 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 10 | NDC:0280-6092-08 | 1 in 1 CARTON | 07/01/2021 | |
| 10 | | 250 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 11 | NDC:0280-6092-09 | 1 in 1 CARTON | 07/01/2021 | |
| 11 | | 90 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 12 | NDC:0280-6092-12 | 10 in 1 VIAL; Type 0: Not a Combination Product | 07/01/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NDA | NDA020204 | 01/26/2018 | |

Labeler - Bayer HealthCare LLC. (112117283)