

**EC-NAPROSYN<sup>®</sup> (naproxen delayed-release tablets), NAPROSYN<sup>®</sup> (naproxen tablets), ANAPROX<sup>®</sup>/ANAPROX<sup>®</sup> DS (naproxen sodium tablets), NAPROSYN<sup>®</sup> (naproxen suspension)**

937 500 mg: white, oblong coated tablets imprinted with NPR EC 500 on one side.  
938 Packaged in light-resistant bottles of 100.

939 100's (bottle): NDC 0004-6416-01.

940 Store at 15° to 30°C (59° to 86°F) in well-closed containers; dispense in light-  
941 resistant containers.

942 **ANAPROX Tablets:** Naproxen sodium 275 mg: light blue, oval-shaped,  
943 engraved with NPS-275 on one side. Packaged in bottles of 100.

944 100's (bottle): NDC 0004-6202-01.

945 Store at 15° to 30°C (59° to 86°F) in well-closed containers.

946 **ANAPROX DS Tablets:** Naproxen sodium 550 mg: dark blue, oblong-  
947 shaped, engraved with NPS 550 on one side and scored on both sides.  
948 Packaged in bottles of 100.

949 100's (bottle): NDC 0004-6203-01.

950 Store at 15° to 30°C (59° to 86°F) in well-closed containers.

951 Revised: September 2007

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953 **Medication Guide**  
954 **for**  
955 **Non-steroidal Anti-Inflammatory Drugs (NSAIDs)**  
956 **(See the end of this Medication Guide for a list of prescription NSAID**  
957 **medicines.)**

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959 **What is the most important information I should know about medicines**  
960 **called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)?**

961 **NSAID medicines may increase the chance of a heart attack or**  
962 **stroke that can lead to death.** This chance increases:

- 963
  - with longer use of NSAID medicines
  - in people who have heart disease

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966 **NSAID medicines should never be used right before or after a**  
967 **heart surgery called a “coronary artery bypass graft (CABG).”**

968 **NSAID medicines can cause ulcers and bleeding in the stomach**  
969 **and intestines at any time during treatment. Ulcers and bleeding:**

- 970
  - can happen without warning symptoms

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971 • may cause death

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**The chance of a person getting an ulcer or bleeding increases with:**

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• taking medicines called “corticosteroids” and “anticoagulants”

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• longer use

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• smoking

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• drinking alcohol

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• older age

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• having poor health

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**NSAID medicines should only be used:**

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• exactly as prescribed

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• at the lowest dose possible for your treatment

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• for the shortest time needed

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**What are Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)?**

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NSAID medicines are used to treat pain and redness, swelling, and heat (inflammation) from medical conditions such as:

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• different types of arthritis

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• menstrual cramps and other types of short-term pain

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**Who should not take a Non-Steroidal Anti-Inflammatory Drug (NSAID)?**

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**Do not take an NSAID medicine:**

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• if you had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAID medicine

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998

• for pain right before or after heart bypass surgery

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**Tell your healthcare provider:**

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• about all of your medical conditions.

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• about all of the medicines you take. NSAIDs and some other medicines can interact with each other and cause serious side effects. **Keep a list of your medicines to show to your healthcare provider and pharmacist.**

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• if you are pregnant. **NSAID medicines should not be used by pregnant women late in their pregnancy.**

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• if you are breastfeeding. **Talk to your doctor.**

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1010 **What are the possible side effects of Non-Steroidal Anti-Inflammatory**  
 1011 **Drugs (NSAIDs)?**

| <b>Serious side effects include:</b>  | <b>Other side effects include:</b>  |
|---|---|
| <ul style="list-style-type: none"> <li>• heart attack</li> <li>• stroke</li> <li>• high blood pressure</li> <li>• heart failure from body swelling (fluid retention)</li> <li>• kidney problems including kidney failure</li> <li>• bleeding and ulcers in the stomach and intestine</li> <li>• low red blood cells (anemia)</li> <li>• life-threatening skin reactions</li> <li>• life-threatening allergic reactions</li> <li>• liver problems including liver failure</li> <li>• asthma attacks in people who have asthma</li> </ul> | <ul style="list-style-type: none"> <li>• stomach pain</li> <li>• constipation</li> <li>• diarrhea</li> <li>• gas</li> <li>• heartburn</li> <li>• nausea</li> <li>• vomiting</li> <li>• dizziness</li> </ul> |

1012 **Get emergency help right away if you have any of the following**  
 1013 **symptoms:**  
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|---|--|
| <ul style="list-style-type: none"> <li>• shortness of breath or trouble breathing</li> <li>• chest pain</li> <li>• weakness in one part or side of your body</li> </ul> | <ul style="list-style-type: none"> <li>• slurred speech</li> <li>• swelling of the face or throat</li> </ul> |
|---|--|

1015 **Stop your NSAID medicine and call your healthcare provider right away**  
 1016 **if you have any of the following symptoms:**  
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- |   |  |
|---|--|
| <ul style="list-style-type: none"> <li>• nausea</li> <li>• more tired or weaker than usual</li> <li>• itching</li> <li>• your skin or eyes look yellow</li> <li>• stomach pain</li> <li>• flu-like symptoms</li> <li>• vomit blood</li> </ul> | <ul style="list-style-type: none"> <li>• there is blood in your bowel movement or it is black and sticky like tar</li> <li>• unusual weight gain</li> <li>• skin rash or blisters with fever</li> <li>• swelling of the arms and legs, hands and feet</li> </ul> |
|---|--|

1018 These are not all the side effects with NSAID medicines. Talk to your  
 1019 healthcare provider or pharmacist for more information about NSAID  
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1021 medicines. Call your doctor for medical advice about side effects. You may  
1022 report side effects to FDA at 1-800-FDA-1088 or Roche at 1-800-526-6367.

1023 **Other information about Non-Steroidal Anti-Inflammatory Drugs**  
1024 **(NSAIDs):**

- 1025 • Aspirin is an NSAID medicine but it does not increase the chance of a  
1026 heart attack. Aspirin can cause bleeding in the brain, stomach, and  
1027 intestines. Aspirin can also cause ulcers in the stomach and intestines.
- 1028 • Some of these NSAID medicines are sold in lower doses without a  
1029 prescription (over-the-counter). Talk to your healthcare provider before  
1030 using over-the-counter NSAIDs for more than 10 days.

1031 **NSAID medicines that need a prescription**  
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| Generic Name   | Tradename   |
|----------------|---|
| Celecoxib      | Celebrex <sup>®</sup>   |
| Diclofenac     | Cataflam <sup>®</sup> , Voltaren <sup>®</sup> , Arthrotec <sup>™</sup> (combined with misoprostol)  |
| Diflunisal     | Dolobid <sup>®</sup>  |
| Etodolac       | Lodine <sup>®</sup> , Lodine <sup>®</sup> XL  |
| Fenoprofen     | Nalfon <sup>®</sup> , Nalfon <sup>®</sup> 200   |
| Flurbiprofen   | Ansaid <sup>®</sup>   |
| Ibuprofen      | Motrin <sup>®</sup> , Tab-Profen <sup>®</sup> , Vicoprofen <sup>®*</sup> (combined with hydrocodone), Combunox <sup>™</sup> (combined with oxycodone)                           |
| Indomethacin   | Indocin <sup>®</sup> , Indocin <sup>®</sup> SR, Indo-Lemmon <sup>™</sup> , Indomethagan <sup>™</sup>  |
| Ketoprofen     | Oruvail <sup>®</sup>  |
| Ketorolac      | Toradol <sup>®</sup>  |
| Mefenamic Acid | Ponstel <sup>®</sup>  |
| Meloxicam      | Mobic <sup>®</sup>  |
| Nabumetone     | Relafen <sup>®</sup>  |
| Naproxen       | Naprosyn <sup>®</sup> , Anaprox <sup>®</sup> , Anaprox <sup>®</sup> DS, EC-Naprosyn <sup>®</sup> , Naprelan <sup>®</sup> , Naprapac <sup>®</sup> (copackaged with lansoprazole) |
| Oxaprozin      | Daypro <sup>®</sup>   |
| Piroxicam      | Feldene <sup>®</sup>  |
| Sulindac       | Clinoril <sup>®</sup>   |
| Tolmetin       | Tolectin <sup>®</sup> , Tolectin DS <sup>®</sup> , Tolectin <sup>®</sup> 600  |

1033 \*Vicoprofen contains the same dose of ibuprofen as over-the-counter (OTC)  
1034 NSAID, and is usually used for less than 10 days to treat pain. The OTC  
1035 NSAID label warns that long term continuous use may increase the risk of  
1036 heart attack or stroke.

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1037 This Medication Guide has been approved by the U.S. Food and Drug  
1038 Administration.

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1042 owners.

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