

EC-NAPROSYN[®] (naproxen delayed-release tablets), NAPROSYN[®] (naproxen tablets), ANAPROX[®]/ANAPROX[®] DS (naproxen sodium tablets), NAPROSYN[®] (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

952

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.)**

958

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

964

965

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

EC-NAPROSYN[®] (naproxen delayed-release tablets), NAPROSYN[®] (naproxen tablets), ANAPROX[®]/ANAPROX[®] DS (naproxen sodium tablets), NAPROSYN[®] (naproxen suspension)

971 • may cause death

972

973

974

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

975

• taking medicines called “corticosteroids” and “anticoagulants”

976

977

• longer use

978

• smoking

979

• drinking alcohol

980

• older age

981

• having poor health

982

983

NSAID medicines should only be used:

984

• exactly as prescribed

985

• at the lowest dose possible for your treatment

986

• for the shortest time needed

987

988

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

989

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

990

991

• different types of arthritis

992

• menstrual cramps and other types of short-term pain

993

994

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

995

Do not take an NSAID medicine:

996

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

997

998

• for pain right before or after heart bypass surgery

999

1000

Tell your healthcare provider:

1001

• about all of your medical conditions.

1002

• 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.**

1003

1004

1005

1006

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

1007

1008

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

1009

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

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

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

1012 **Get emergency help right away if you have any of the following**
 1013 **symptoms:**
 1014

- | | |
|---|--|
| <ul style="list-style-type: none"> • shortness of breath or trouble breathing • chest pain • weakness in one part or side of your body | <ul style="list-style-type: none"> • slurred speech • swelling of the face or throat |
|---|--|

1015 **Stop your NSAID medicine and call your healthcare provider right away**
 1016 **if you have any of the following symptoms:**
 1017

- | | |
|---|--|
| <ul style="list-style-type: none"> • nausea • more tired or weaker than usual • itching • your skin or eyes look yellow • stomach pain • flu-like symptoms • vomit blood | <ul style="list-style-type: none"> • there is blood in your bowel movement or it is black and sticky like tar • unusual weight gain • skin rash or blisters with fever • swelling of the arms and legs, hands and feet |
|---|--|

1018 **These are not all the side effects with NSAID medicines. Talk to your**
 1019 **healthcare provider or pharmacist for more information about NSAID**
 1020

EC-NAPROSYN[®] (naproxen delayed-release tablets), NAPROSYN[®] (naproxen tablets), ANAPROX[®]/ANAPROX[®] DS (naproxen sodium tablets), NAPROSYN[®] (naproxen suspension)

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**
1032

Generic Name	Tradename
Celecoxib	Celebrex [®]
Diclofenac	Cataflam [®] , Voltaren [®] , Arthrotec [™] (combined with misoprostol)
Diflunisal	Dolobid [®]
Etodolac	Lodine [®] , Lodine [®] XL
Fenoprofen	Nalfon [®] , Nalfon [®] 200
Flurbiprofen	Ansaid [®]
Ibuprofen	Motrin [®] , Tab-Profen [®] , Vicoprofen ^{®*} (combined with hydrocodone), Combunox [™] (combined with oxycodone)
Indomethacin	Indocin [®] , Indocin [®] SR, Indo-Lemmon [™] , Indomethagan [™]
Ketoprofen	Oruvail [®]
Ketorolac	Toradol [®]
Mefenamic Acid	Ponstel [®]
Meloxicam	Mobic [®]
Nabumetone	Relafen [®]
Naproxen	Naprosyn [®] , Anaprox [®] , Anaprox [®] DS, EC-Naprosyn [®] , Naprelan [®] , Naprapac [®] (copackaged with lansoprazole)
Oxaprozin	Daypro [®]
Piroxicam	Feldene [®]
Sulindac	Clinoril [®]
Tolmetin	Tolectin [®] , Tolectin DS [®] , Tolectin [®] 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.

EC-NAPROSYN[®] (naproxen delayed-release tablets), NAPROSYN[®] (naproxen tablets), ANAPROX[®]/ANAPROX[®] DS (naproxen sodium tablets), NAPROSYN[®] (naproxen suspension)

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

1039 Medication Guide Revised: Month Year

1040

1041 All registered trademarks in this document are the property of their respective
1042 owners.

1043 Distributed by:



Pharmaceuticals

Roche Laboratories Inc.
340 Kingsland Street
Nutley, New Jersey 07110-1199

1044

1045

1046 XXXXXXXXX

1047

1048 Copyright © 1999-200X by Roche Laboratories Inc. All rights reserved.