Nalfon may be administered with meals or with milk. Although the total amount absorbed is not affected, peak blood levels are delayed and diminished.

Patients with rheumatoid arthritis generally seem to require larger doses of Nalfon than do those with osteoarthritis. The smallest dose that yields acceptable control should be employed.

Although improvement may be seen in a few days in many patients, an additional 2 to 3 weeks may be required to gauge the full benefits of therapy.

#### HOW SUPPLIED

Nalfon® (fenoprofen calcium capsules, USP) are available in:

The **200 mg\*** capsule is opaque yellow No. 97 cap and opaque white body, imprinted with "RX681" on the cap and body.

NDC 0884-6600-10

Bottles of 100

The **400 mg\*** capsule is opaque green cap and opaque blue body, imprinted with "NALFON 400 mg" on the cap and "EP 123" on the body.

NDC 0884-7308-09

Bottles of 90

NDC 0884-7308-50

Bottles of 500

### \* Equivalent to fenoprofen.

Preserve in well-closed containers.

Store at 20° - 25° C (68° - 77° F). (See USP Controlled Room Temperature). **ATTENTION DISPENSER: Accompanying Medication Guide <u>must</u> be dispensed with this product.** 

Nalfon® (nal-fon) capsules generic name: fenoprofen calcium

### Medication Guide

For

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

(See the end of this Medication Guide for a list of prescription NSAID medicines.)

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

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

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

## NSAID medicines should never be used right before or after a heart surgery called a "coronary artery bypass graft (CABG)."

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

- can happen without warning symptoms
- may cause death

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

- taking medicines called "corticosteroids" and "anticoagulants"
- longer use
- smoking
- · drinking alcohol
- older age
- having poor health

### NSAID medicines should only be used:

- exactly as prescribed
- at the lowest dose possible for your treatment
- for the shortest time needed

### What are Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)? NSAID medicines are used to treat pain and redness, swelling, and heat (inflammation) from medical conditions such as:

- different types of arthritis
- menstrual cramps and other types of short-term pain

### Who should not take a Non-Steroidal Anti-Inflammatory Drug (NSAID)? Do not take an NSAID medicine:

- if you had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAID medicine
- for pain right before or after heart bypass surgery

### Tell your healthcare provider:

- about all of your medical conditions.
- 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.**
- if you are pregnant, NSAID medicines should not be used past 30-weeks of pregnancy.
- if you are breastfeeding, talk to your doctor.

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

Serious side effects include:	Other side effects include:

- · 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

- stomach pain
- constipation
- diarrhea
- gas
- heartburn
- nausea
- vomiting
- dizziness

### Get emergency help right away if you have any of the following symptoms:

- shortness of breath or trouble breathing
- chest pain
- weakness in one part or side of your body
- · slurred speech
- swelling of the face or throat

## Stop your NSAID medicine and call your healthcare provider right away if you have any of the following symptoms:

- nausea
- · more tired or weaker than usual
- itching
- your skin or eyes look yellow
- stomach pain
- flu-like symptoms
- vomit blood
- 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

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

### Other information about Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

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

### **NSAID** medicines that need a prescription

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-Naproxyn,
	Naprelan, Naprapac (copackaged with
	lansoprazole)
Oxaprozin	Daypro
Piroxicam	Feldene
Sulindac	Clinoril
Tolmetin	Tolectin, Tolectin DS, Tolectin 600

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

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

Manufactured for:

Pedinol Pharmacal Inc.

Farmingdale, NY 11735 USA

By: Ohm Laboratories, Inc.

North Brunswick, NJ 08902 USA

And

By: Emcure Pharmaceuticals USA, Inc.

East Brunswick, NJ 08816 USA

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