100 mg, NDC 0008-0821, opaque pink and dark-green capsule marked with two radial bands and "ORUVAIL 100" in bottles of 100 capsules.

150 mg, NDC 0008-0822, opaque pink and light-green capsule marked with two radial bands and "ORUVAIL 150" in bottles of 100 capsules.

200 mg, NDC 0008-0690, opaque pink and off-white capsule marked with two radial bands and "ORUVAIL 200" in bottles of 100 capsules and in Redipak® cartons each containing 10 blister strips of 10 capsules.

Keep tightly closed.

Store at room temperature, approximately 25 °C (77 °F).

Dispense in a tight container.

Oruvail capsules should be protected from direct light and excessive heat and humidity.

The appearance of these capsules is a registered trademark of Wyeth Pharmaceuticals. By arrangement with Rhone-Poulenc Rorer France.

Orudis Capsules manufactured and distributed by Wyeth Pharmaceuticals

Oruvail Capsules distributed by Wyeth Pharmaceuticals

Wyeth®

Wyeth Pharmaceuticals Inc. Philadelphia, PA 19101

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 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 by pregnant women late in their 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 stomach pain stroke constipation • high blood pressure diarrhea • heart failure from body swelling (fluid retention) gas • kidney problems including kidney failure heartburn • bleeding and ulcers in the stomach and intestine nausea • low red blood cells (anemia) vomiting · life-threatening skin reactions dizziness life-threatening allergic reactions liver problems including liver failure asthma attacks in people who have asthma

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		
Flurbirofen	Ansaid		
<mark>Ibuprofen</mark>	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 60)0	
	same dose of ibuprofen as over-the-counter (O oel warns that long term continuous use may in		

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

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