

Instruct patients not to apply PENNSAID to open skin wounds, infections, inflammations, or exfoliative dermatitis, as it may affect absorption and reduce tolerability of the drug.

Instruct patients to wait until the area treated with PENNSAID is completely dry before applying sunscreen, insect repellent, lotion, moisturizer, cosmetics, or other topical medication.

Instruct patients to minimize or avoid exposure of treated knee(s) to natural or artificial sunlight.

17.6 Weight Gain and Edema

Instruct patients to promptly report to their physician signs or symptoms of unexplained weight gain or edema following treatment with PENNSAID [see *Warnings and Precautions (5.5)*].

17.7 Anaphylactoid Reactions

Inform patients of the signs of an anaphylactoid reaction (e.g., difficulty breathing, swelling of the face or throat). If these occur, instruct patients to seek immediate emergency help [see *Warnings and Precautions (5.7)*].

17.8 Effects During Pregnancy

Instruct patients who are pregnant or intending to become pregnant not to use PENNSAID [see *Use in Specific Populations (8.1) and Impairment of Fertility (13.1)*].

17.9 Eye Exposure

Instruct patients to avoid contact of PENNSAID with the eyes and mucosa. Advise patients that if eye contact occurs, immediately wash out the eye with water or saline and consult a physician if irritation persists for more than an hour.

17.10 Medication Guide

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 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)?

<p>Serious side effects include:</p> <ul style="list-style-type: none"> • heart attack • stroke • high blood pressure 	<p>Other side effects include:</p> <ul style="list-style-type: none"> • stomach pain • constipation • diarrhea
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<ul style="list-style-type: none"> • 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"> • gas • heartburn • nausea • vomiting • dizziness
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Get emergency help right away if you have any of the following symptoms:

- shortness of breath or trouble breathing
- chest pain
- slurred speech
- weakness in one part or side of your body
- 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.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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
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Celecoxib	Celebrex [®]
Diclofenac	Flector, Cataflam [®] , Voltaren [®] , Arthrotec [™] (combined with misoprostol), PENNSAID [®]
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

*Vicoprofen contains the same dose of ibuprofen as over-the-counter (OTC) NSAID, 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.

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

17.11 Patient Instructions for Use

Patient Instructions for Use PENNSAID [pen/sed] (diclofenac sodium topical solution)

Your doctor has prescribed PENNSAID[®] to treat your pain from osteoarthritis in your knee(s) and help you manage your daily activities better.

Before you use PENNSAID[®]:

- Apply PENNSAID[®] exactly as your doctor tells you. Do not apply PENNSAID[®] anywhere on your body other than where your doctor tells you.
- Apply PENNSAID[®] on clean, dry skin that does not have any cuts, infections or rashes.
- Use PENNSAID[®] 4 times each day on your knee(s).

- Do not get PENNSAID[®] in your eyes, nose or mouth. Only use PENNSAID[®] on your skin (topical use). If you get PENNSAID[®] in your eyes, rinse your eyes right away with water or saline. Call your doctor if your eyes are irritated for more than one hour.

Steps for using PENNSAID[®]:

Step 1. Wash your hands with soap and water before and after applying PENNSAID[®].

Step 2. Your total dose for each knee is 40 drops of PENNSAID[®]. You will use 10 drops at a time. Put 10 drops of PENNSAID[®] **either** on your hand **or** directly on your knee.

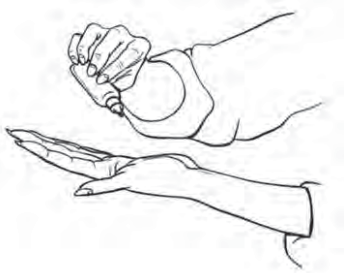


Figure 1. Dispense 10 drops of PENNSAID[®] at a time

Step 3. Spread PENNSAID[®] evenly on the front, back and sides of your knee.

Repeat this step 4 times so that your knee is completely covered with a **total** of 40 drops of PENNSAID[®].

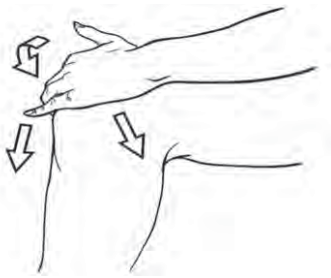


Figure 2. Spread PENNSAID[®] evenly on the front, and sides of your knee



Figure 3. Spread PENNSAID[®] evenly on the back of your knee

Step 4. Repeat steps 2 and 3 for the other knee if needed.

After you use PENNSAID[®]:

Do not

- cover your knee with clothing until your knee is completely dry

- put sunscreen, insect repellent, lotion, moisturizer, cosmetics, or other topical medicines on your knee until it is completely dry
- take a shower or a bath for at least 30 minutes after you put PENNSAID[®] on your knee(s)
- use heating pads or apply bandages to the skin where you have applied PENNSAID[®]
- expose your skin to sunlight or artificial light (tanning booths) where you have put PENNSAID[®]

How should I store PENNSAID[®]?

- Store PENNSAID[®] between 59°F to 86°F (15°C to 30°C).

Keep PENNSAID[®] and all medicines out of the reach of children.

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