

**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

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**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 healthcare provider.**

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

<b>Serious 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>	<b>Other side effects include:</b> <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>
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**Get emergency help right away if you have any of the following 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> |
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**Stop your NSAID medicine and call your healthcare provider right away 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> |
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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
Celecoxib	Celebrex <sup>®</sup>
Diclofenac	Flector <sup>®</sup> , Cataflam <sup>®</sup> , Cambia <sup>®</sup> , Voltaren <sup>®</sup> , Voltaren <sup>®</sup> Gel, Arthrotec <sup>®</sup> (combined with misoprostol), Pennsaid <sup>®</sup> , Zipsor <sup>®</sup> , Zorvolex <sup>™</sup>
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), Duexis <sup>®</sup> (combined with famotidine)
Indomethacin	Indocin <sup>®</sup> , Indocin <sup>®</sup> SR, Indo-Lemmon <sup>™</sup> , Indomethagan <sup>™</sup>
Ketoprofen	Oruvail <sup>®</sup> , Nexcede <sup>™</sup>
Ketorolac	Toradol <sup>®</sup> , Sprix <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> (co-packaged with lansoprazole), Treximet <sup>®</sup> (combined with sumatriptan succinate), Vimovo <sup>®</sup> (combined with esomeprazole magnesium)
Oxaprozin	Daypro <sup>®</sup>
Piroxicam	Feldene <sup>®</sup>
Sulindac	Clinoril <sup>®</sup>
Tolmetin	Tolectin <sup>®</sup> , Tolectin <sup>®</sup> DS, Tolectin <sup>®</sup> 600

\*Vicoprofen<sup>®</sup> 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.

**Carton**



## Instructions for Use

VOLTAREN<sup>®</sup> GEL (diclofenac sodium)

**Important: Use the dosing card that is inside the VOLTAREN<sup>®</sup> GEL carton to correctly measure each dose. The dosing card is re-usable. Do not throw the dosing card away. Before you use VOLTAREN<sup>®</sup> GEL for the first time, your healthcare provider or pharmacist should show you how to correctly measure your dose using the dosing card.**

Read this **Instructions for Use** before you start using VOLTAREN<sup>®</sup> GEL and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Your healthcare provider has prescribed VOLTAREN<sup>®</sup> GEL to help relieve arthritis pain in some of your joints. VOLTAREN<sup>®</sup> GEL may be used to treat arthritis pain in the arms (hands, wrists, and elbows) and in the legs (feet, ankles, and knees). It is not known if VOLTAREN<sup>®</sup> GEL is safe and effective if used on your spine, hips, or shoulders.

- Use VOLTAREN<sup>®</sup> GEL exactly how your healthcare provider prescribes it for you. Do not apply VOLTAREN<sup>®</sup> GEL anywhere other than where your doctor tells you to.
- **Do not use more than a total of 32 grams of VOLTAREN<sup>®</sup> GEL each day. If you add up the amount of VOLTAREN<sup>®</sup> GEL as directed by your healthcare provider, it should not be more than 32 grams in one day.**

**The dose for your hands, wrists, or elbows is 2 grams of VOLTAREN<sup>®</sup> GEL each time you apply it.**

- Apply VOLTAREN<sup>®</sup> GEL 4 times a day (a total of 8 grams each day). Do not apply more than 8 grams each day to any one of your affected hands, wrists, or elbows.

**The dose for your feet, ankles, or knees is 4 grams of VOLTAREN<sup>®</sup> GEL each time you apply it.**

- Apply VOLTAREN<sup>®</sup> GEL 4 times a day (a total of 16 grams each day). Do not apply more than 16 grams each day to any one of your affected knees, ankles, or feet.

**Some examples of VOLTAREN<sup>®</sup> GEL applications include:**

- If you use 2 grams of VOLTAREN<sup>®</sup> GEL on one hand, 4 times a day, your total dose for one day is 8 grams
- If you use 4 grams of VOLTAREN<sup>®</sup> GEL on one knee, 4 times a day, your total dose for one day is 16 grams.
- Your total dose for one day, treating one hand and one knee, is 8 grams plus 16 grams, which equals 24 grams of VOLTAREN<sup>®</sup> GEL.

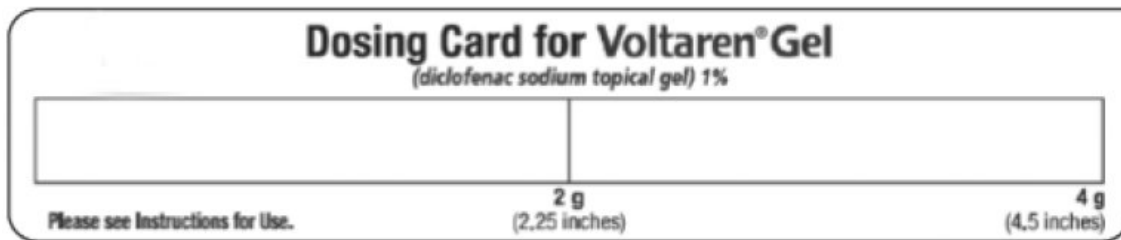


Figure A

- Before you use a new tube of VOLTAREN<sup>®</sup> GEL for the first time, open the foil seal that covers the tube opening by using the spiked top of the cap. Remember to remove the dosing card from the carton to measure your dose (See Figure A).
- Apply VOLTAREN<sup>®</sup> GEL to clean, dry skin that does not have any cuts, infections or rashes.
- Do not use heating pads or apply bandages where you have applied VOLTAREN<sup>®</sup> GEL.
- Avoid exposing skin where you apply VOLTAREN<sup>®</sup> GEL to sunlight and artificial light, such as tanning booths.
- Do not use sunscreens, cosmetics, lotions, moisturizers, insect repellants, or other topical medicines on the same skin areas where you have applied VOLTAREN<sup>®</sup> GEL.
- Do not get VOLTAREN<sup>®</sup> GEL in your eyes, nose, or mouth. VOLTAREN<sup>®</sup> GEL is only to be used on your skin (topical use). If you get VOLTAREN<sup>®</sup> GEL in your eyes, rinse your eyes right away with water or saline. Talk with your healthcare provider if eye irritation lasts for more than one hour.

**What if I miss a dose:**

- If you miss a dose of VOLTAREN<sup>®</sup> GEL, continue with your next scheduled dose using the prescribed amount of VOLTAREN<sup>®</sup> GEL. **Do not double the dose.**

**Applying 2 grams (2 g) of VOLTAREN<sup>®</sup> GEL to hands, wrists, or elbows:**

**Step 1.** Remove the dosing card that is attached inside the VOLTAREN<sup>®</sup> GEL carton. Use the dosing card to correctly measure each dose of VOLTAREN<sup>®</sup> GEL. To measure the correct amount of VOLTAREN<sup>®</sup> GEL, place the dosing card on a flat surface so that you can read the print. If the print is backwards, flip dosing card over (See Figure A). If you lose or misplace your dosing card, you can ask your pharmacist for a new one or call 1-800-398-5876. Ask your healthcare provider or pharmacist to show you how to correctly measure your dose of VOLTAREN<sup>®</sup> GEL while you are waiting to receive your new dosing card.

**Step 2.** Squeeze VOLTAREN<sup>®</sup> GEL onto the dosing card evenly, up to the 2 g line (a 2.25 inch length of gel). Make sure that the gel covers the entire 2 gram area of the dosing card (See Figure B). Put the cap back on the tube of VOLTAREN<sup>®</sup> GEL. Ask your healthcare provider or pharmacist if you are not sure how to correctly measure your dose of VOLTAREN<sup>®</sup> GEL.

**Step 3.** Apply the gel to your hand, wrist, or elbow. You can use the dosing card to apply the gel (See Figure C). Then, use your hands to gently rub the gel into the skin (See Figure D). Do not share your dosing card with another person. Make sure to cover the entire affected hand, wrist or elbow with the gel. Remember that the hand includes the palm of your hand, the top of your hand, and your fingers.

**Step 4.** After using the dosing card, hold end with fingertips, rinse and dry. **Store the dosing card until next use.** Do not shower or bathe for at least 1 hour after applying VOLTAREN<sup>®</sup> GEL. Do not wash your treated hands for at least 1 hour after applying the VOLTAREN<sup>®</sup> GEL.

**Step 5.** After applying VOLTAREN<sup>®</sup> GEL, wait 10 minutes before covering the treated skin with gloves or clothing.



Figure B

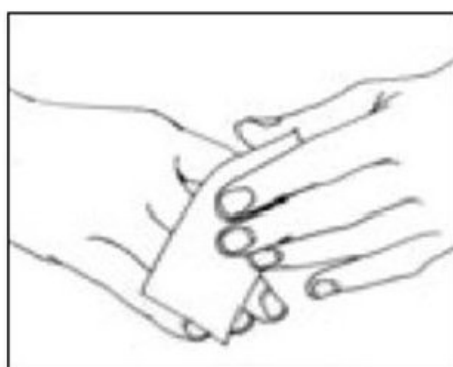


Figure C

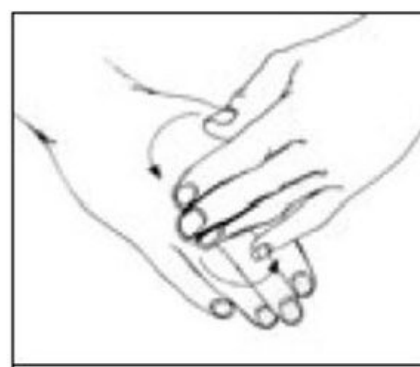


Figure D

**Applying 4 grams (4 g) of VOLTAREN<sup>®</sup> GEL to feet, ankles, or knees:**

- **Step 1.** Refer to **Step 1** above.

**Step 2.** Squeeze VOLTAREN<sup>®</sup> GEL onto the dosing card evenly up to the 4 g line (a 4.5 inch length of gel), making sure the gel covers the 4 g area of the dosing card (See Figure E). Put the cap back on the tube of VOLTAREN<sup>®</sup> GEL. Ask your healthcare provider or pharmacist if you are not sure how to correctly measure your dose of VOLTAREN<sup>®</sup> GEL.

**Step 3.** Apply VOLTAREN<sup>®</sup> GEL to your foot, ankle, or knee. You can use the dosing card to apply the gel (See Figure F). Then, use your hands to gently rub the gel into the skin (See Figure G). Do not share your dosing card with another person. Make sure to cover your entire foot, ankle, or knee

area with the gel. For example, cover the skin above, below, inside and outside the knee cap. Remember that the foot includes the sole of your foot, the top of your foot and your toes.

**Refer to Steps 4 and 5 above.** Wash your hands after applying VOLTAREN<sup>®</sup> GEL to your foot, ankle, or knee.

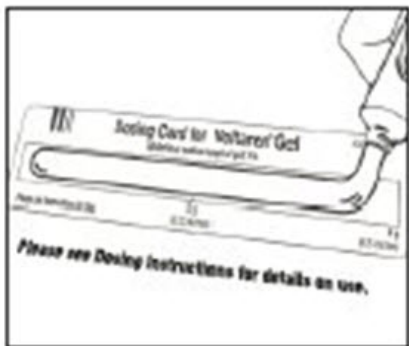


Figure E



Figure F



Figure G

**What are the ingredients in VOLTAREN<sup>®</sup> GEL?**

**Active ingredient:** diclofenac sodium

**Inactive ingredients:** carbomer homopolymer Type C, cocoyl caprylocaprates, fragrance, isopropyl alcohol, mineral oil, polyoxyl 20 cetostearyl ether, propylene glycol, purified water, and strong ammonia solution.

**How should I store VOLTAREN<sup>®</sup> GEL?** Store at 20°C to 25°C (68°F to 77°F). Do not freeze VOLTAREN<sup>®</sup> GEL. Store the dosing card with your VOLTAREN<sup>®</sup> GEL.

**Keep VOLTAREN<sup>®</sup> GEL, the dosing card, and all medicines out of the reach of children.**

This Medication Guide and Instructions for Use have been approved by the U.S. Food and Drug Administration.

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