

Medication Guide for Nonsteroidal Anti-inflammatory Drugs (NSAIDs)

What is the most important information I should know about medicines called Nonsteroidal Anti-inflammatory Drugs (NSAIDs)?

NSAIDs can cause serious side effects, including:

- **Increased risk of a heart attack or stroke that can lead to death.** This risk may happen early in treatment and may increase:
 - with increasing doses of NSAIDs
 - with longer use of NSAIDs

Do not take NSAIDs right before or after a heart surgery called a “coronary artery bypass graft (CABG).”

Avoid taking NSAIDs after a recent heart attack, unless your healthcare provider tells you to. You may have an increased risk of another heart attack if you take NSAIDs after a recent heart attack.

- **Increased risk of bleeding, ulcers, and tears (perforation) of the esophagus (tube leading from the mouth to the stomach), stomach and intestines:**
 - anytime during use
 - without warning symptoms
 - that may cause death

The risk of getting an ulcer or bleeding increases with:

- past history of stomach ulcers, or stomach or intestinal bleeding with use of NSAIDs
- taking medicines called “corticosteroids”, “anticoagulants”, “SSRIs”, or “SNRIs”
- increasing doses of NSAIDs
- longer use of NSAIDs
- smoking
- drinking alcohol
- older age
- poor health
- advanced liver disease
- bleeding problems

NSAIDs should only be used:

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

What are NSAIDs?

NSAIDs 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 NSAIDs?

Do not take NSAIDs:

- if you have had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAIDs.
- right before or after heart bypass surgery.

Before taking NSAIDs, tell your health care provider about all of your medical conditions, including if you:

- have liver or kidney problems
- have high blood pressure
- have asthma
 - are pregnant or plan to become pregnant. Talk to your health care provider if you are considering taking NSAIDs during pregnancy. You should not take NSAIDs after 29 weeks of pregnancy.
 - are breastfeeding or plan to breast feed.

Tell your health care provider about all of the medicines you take, including prescription or over-the-counter medicines, vitamins or herbal supplements. NSAIDs and some other medicines can interact with each other and cause serious side effects. **Do not start taking new medicine without talking to your health care provider first.**

What are the possible side effects of NSAIDs?

NSAIDs can cause serious side effects, including:

See “What is the most important information I should know about medicines called Nonsteroidal Anti-inflammatory Drugs (NSAIDs)?”

- new or worse high blood pressure
- heart failure
- liver problems including liver failure
- kidney problems including kidney failure
- low red blood cells (anemia)
- life-threatening skin reactions
- life-threatening allergic reactions
- Other side effects of NSAIDs include: stomach pain, constipation, diarrhea, gas, heartburn, nausea, vomiting and dizziness.

Get emergency help right away if you get 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 taking your NSAID and call your health care provider right away if you get any of the following symptoms:

- nausea
- more tired or weaker than usual
- diarrhea
- itching
- your skin or eyes look yellow

indigestion or 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, legs, hands, and feet

If you take too much of your NSAID, call your health care provider or get medical help right away.

These are not all the possible side effects of NSAIDs. For more information, ask your health care provider or pharmacist about NSAIDs.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA1088.

Other information about NSAIDs

- Aspirin is an NSAID 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 NSAIDs are sold in lower doses without a prescription (over-the-counter). Talk to your health care provider before using over-the-counter NSAIDs for more than 10 days.

General information about the safe and effective use of NSAIDs

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use NSAIDs for a condition for which it was not prescribed. Do not give NSAIDs to other people, even if they have the same symptoms that you have. It may harm them.

If you would like more information about NSAIDs, talk with your health care provider. You can ask your pharmacist or health care provider for information about NSAIDs that is written for health professionals.

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For more information, go to www.amneal.com or call 1-877-835-5472.

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

Instructions for Use

Diclofenac (dye-KLOE-fen-ak) Sodium Topical Gel, 1%

Important: Use the dosing card that is inside the diclofenac sodium topical gel carton to correctly measure each dose. The dosing card is re-usable. Do not throw the dosing card away. Before you use diclofenac sodium topical 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 diclofenac sodium topical 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 diclofenac sodium topical gel to help relieve arthritis pain in some of your joints. Diclofenac sodium topical 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 diclofenac sodium topical gel is safe and effective if used on your spine, hips, or shoulders.

- Use diclofenac sodium topical gel exactly how your healthcare provider prescribes it for you. Do not apply diclofenac sodium topical gel anywhere other than where your healthcare provider tells you to.
- **Do not use more than a total of 32 grams of diclofenac sodium topical gel each day. If you add up the amount of diclofenac sodium topical 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 diclofenac sodium topical gel each time you apply it.

- Apply diclofenac sodium topical 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 diclofenac sodium topical gel each time you apply it.

- Apply diclofenac sodium topical 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 feet, ankles, or knees.

Some examples of diclofenac sodium topical gel application include:

- If you use 2 grams of diclofenac sodium topical gel on one hand, 4 times a day, your total dose for one day is 8 grams.
- If you use 4 grams of diclofenac sodium topical 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 diclofenac sodium topical gel.

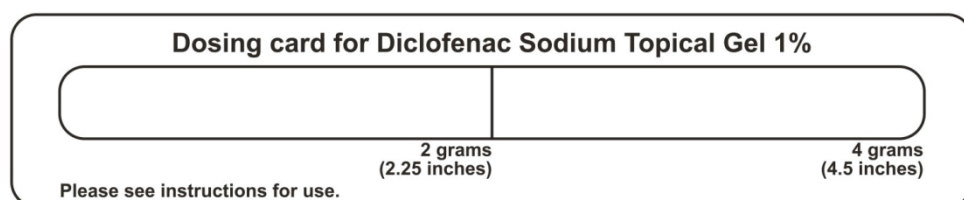


Figure A

- Before you use a new tube of diclofenac sodium topical 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 diclofenac sodium topical gel to clean, dry skin that does not have any cuts, open wounds, infections, or rashes.
- Do not use heating pads or apply bandages to where you have applied diclofenac sodium topical gel.
- Avoid exposing skin where you apply diclofenac sodium topical 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 diclofenac sodium topical gel.
- Do not get diclofenac sodium topical gel in your eyes, nose, or mouth. Diclofenac sodium topical gel is only to be used on your skin (topical use). If you get diclofenac sodium topical 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 diclofenac sodium topical gel, continue with your next scheduled dose using the prescribed amount of diclofenac sodium topical gel. **Do not double the dose.**

Applying 2 grams (2 g) of diclofenac sodium topical gel to hands, wrists, or elbows:

Step 1. Remove the dosing card that is attached inside the diclofenac sodium topical gel carton. Use the dosing card to correctly measure each dose of diclofenac sodium topical gel. To measure the correct amount of diclofenac sodium topical 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 1-877-835-5472. Ask your healthcare provider or pharmacist to show you how to correctly measure your dose of diclofenac sodium topical gel while you are waiting to receive your new dosing card.

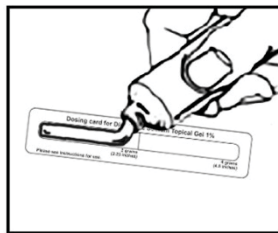


Figure B



Figure C



Figure D

Step 2. Squeeze diclofenac sodium topical 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 2 g area of the dosing card (see Figure B). Put the cap back on the tube of diclofenac sodium topical gel. Ask your healthcare provider or pharmacist if you are not sure how to correctly measure your dose of diclofenac sodium topical 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 diclofenac sodium topical gel. Do not wash your treated hands for at least 1 hour after applying the diclofenac sodium topical gel.

Step 5. After applying diclofenac sodium topical gel, wait 10 minutes before covering the treated skin with gloves or clothing.

Applying 4 grams (4 g) of diclofenac sodium topical gel to feet, ankles, or knees:

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

Step 2. Squeeze diclofenac sodium topical 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 diclofenac sodium topical gel. Ask your healthcare provider or pharmacist if you are not sure how to correctly measure your dose of diclofenac sodium topical gel.

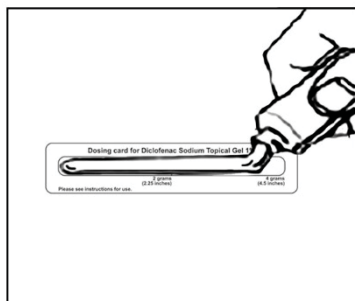


Figure E



Figure F



Figure G

Step 3. Apply diclofenac sodium topical 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 diclofenac sodium topical gel to your foot, ankle, or knee.

What are the ingredients in diclofenac sodium topical gel?

Active ingredient: diclofenac sodium

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

How should I store diclofenac sodium topical gel?

Store at 20°C to 25°C (68°F to 77°F). Do not freeze diclofenac sodium topical gel. Store the dosing card with your diclofenac sodium topical gel.

Keep diclofenac sodium topical 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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