

in adverse reactions such as, and toxic epidermal necrolysis occur without warning. Inform reactions, and to discontinue the e of skin rash or any other sign of 4)].

ductus arteriosus. Avoid use of infant women starting at 30 weeks (8.1)].

ly be due to occult or gross blood et on erythropoiesis. If a patient or symptoms of anemia, monitor

ease the risk of bleeding events. concomitant use of warfarin, other nism reuptake inhibitors (SSRIs) ) may increase this risk. Monitor (7)].

al gel in reducing inflammation, gns in detecting infections.

injury can occur without warning g-term NSAID treatment with a d Precautions (5.2, 5.3, 5.6)].

artificial sunlight on treated areas treatment resulted in an earlier ial effects of diclofenac sodium are not known.

mucosa, although not studied, e contact occurs, they should consult a physician if irritation

in a higher rate of hemorrhage, obin. Do not use combination AID unless the benefit outweighs

er detail in other sections of the

and Precautions (5.1)]  
ings and Precautions (5.2)]  
3)]  
cautions (5.5)]  
and Precautions (5.6)]  
utions (5.7)]  
ions (5.9)]  
ons (5.11)]

ng conditions, adverse reaction ectly compared with rates in the bserved in practice.

to diclofenac sodium topical gel olled, parallel-group studies in Of these, 513 patients received (nee and 400 were treated for a exposed to diclofenac sodium fely trial in osteoarthritis of the s of 1 knee and 228 were treated ged from 8 to 12 weeks for the en-label safety trial.

ed with diclofenac sodium topical during the short-term placebo- al and placebo (vehicle gel) over- ation site reactions. These were patients with a greater frequency cebo group (2%).

1. Application site dermatitis was s reported by 4% of patients % of placebo patients.

ions (≥1% diclofenac sodium

**Increased risk of bleeding, ulcers, and tears (perforation) of the esophagus (tube leading from the mouth to the stomach), stomach and intestines:**

- o anytime during use
- o without warning symptoms
- o that may cause death

**The risk of getting an ulcer or bleeding increases with:**

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

**NSAIDs should only be used:**

- o exactly as prescribed
- o at the lowest dose possible for your treatment
- o 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 healthcare 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 healthcare 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 healthcare 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 any new medicine without talking to your healthcare 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:**

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

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

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

**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 healthcare provider. You can ask your pharmacist or healthcare provider for information about NSAIDs that is written for health professionals.

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**Distributed by:**  
**Encube Ethicals, Inc.**  
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Durham, NC 27713 USA

This Medication Guide has been approved by the U.S. Food and Drug Administration.  
Revised: December 2019

**Instructions for Use**  
Diclofenac 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**

Diclofenac sodium topical gel	Placebo (vehicle) N=876
	N (%)
	19 (2)
	6 (<1)
	1 (<1)
	3 (<1)
	3 (<1)
	3 (<1)
	0
	0
	0



**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.
- 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)

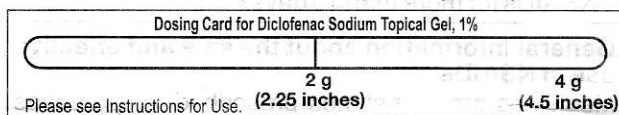


Figure A

- 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 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.

**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.

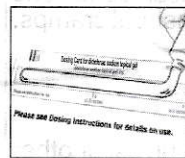


Figure E



Figure F



Figure G

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

In the placebo-for patients treated group. Application frequent reason

Long-Term Open In the open-label that in the placebo year with diclofenac observed in 119 drug were expected discontinuation of patients.

7 DRUG See Table 2 for

Table 2: Clinical

Drugs That Clinical Impact:

Intervention:

Aspirin Clinical Impact:

Intervention:

ACE Inhibitor Clinical Impact:

Intervention:

Diuretics Clinical Impact:

Intervention:

Digoxin Clinical Impact:

Intervention:

Lithium Clinical Impact:

Intervention:

Methotrexate Clinical Impact:

Intervention:

Cyclosporine Clinical Impact:

Intervention:

NSAIDs and S Clinical Impact:

Intervention: