

Medication Guide

Diclofenac (dye-KLOE-fen-ak) Sodium Gel, 3%

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

Diclofenac Sodium Gel is an NSAID medicine that is used on the skin only (topical). Do not use Diclofenac Sodium Gel in or on the eyes.

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:

- o with increasing doses of NSAIDs
- o with longer use of NSAIDs

Do not take or use 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 or use 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:**

- 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 problems

NSAIDs should only be used:

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

What is Diclofenac Sodium Gel?

Diclofenac Sodium Gel is an NSAID that is used on the skin (topical) to treat a skin condition called actinic keratosis.

Diclofenac Sodium Gel is not for use in children.

Who should not use Diclofenac Sodium Gel?

Do not use Diclofenac Sodium Gel:

- if you have had an allergic reaction to any of the ingredients in Diclofenac Sodium Gel. See the end of this Medication Guide for a complete list of ingredients in Diclofenac Sodium Gel.
- right before or after heart bypass surgery.

Before using Diclofenac Sodium Gel, 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 or use NSAIDs after 29 weeks of pregnancy.**
- are breastfeeding or plan to breastfeed. You and your healthcare provider should decide if you will use Diclofenac Sodium Gel or breastfeed. You should not do both.

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.**

How should I use Diclofenac Sodium Gel?

- Use Diclofenac Sodium Gel exactly as your healthcare provider tells you to use it.
- Apply Diclofenac Sodium Gel 2 times a day.
- Apply enough Diclofenac Sodium Gel to cover each skin lesion and gently rub in.
- Diclofenac Sodium Gel may be used for 60 to 90 days. You may not see improvement of skin lesions for up to 30 days after stopping treatment. See your healthcare provider if lesions do not respond to treatment.
- Wash your hands after applying Diclofenac Sodium Gel.

What should I avoid while using Diclofenac Sodium Gel?

- Avoid spending time in sunlight or artificial light, such as tanning beds or sunlamps. Diclofenac Sodium Gel can make your skin sensitive to sunlight and the light from tanning beds and sunlamps.
- You should avoid applying Diclofenac Sodium Gel to open skin wounds, skin infections, or peeling skin.

What are the possible side effects of Diclofenac Sodium Gel?

Diclofenac Sodium Gel and other NSAIDs can cause serious side effects, including:

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

- new or worse high blood pressure
- liver problems including liver failure
- low red blood cells (anemia)
- life threatening allergic reactions
- heart failure
- kidney problems including kidney failure
- life-threatening skin 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 using Diclofenac Sodium Gel and call your healthcare 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

Application site skin reactions are common with Diclofenac Sodium Gel and include: skin redness, itching, rash, dry skin, scaling, and peeling.

If Diclofenac Sodium Gel is accidentally taken by mouth, 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 healthcare provider before using over-the-counter NSAIDs for more than 10 days.

How should I store Diclofenac Sodium Gel?

- Store Diclofenac Sodium Gel at room temperature 68°F to 77°F (20°C to 25°C).
- Keep Diclofenac Sodium Gel away from heat. Avoid freezing Diclofenac Sodium Gel.

Keep Diclofenac Sodium Gel and all medicines out of the reach of children.

General information about the safe and effective use of Diclofenac Sodium Gel

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

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

What are the ingredients in Diclofenac Sodium Gel?

Active ingredient: diclofenac sodium

Inactive ingredients: benzyl alcohol, hyaluronate sodium, polyethylene glycol monomethyl ether, and purified water.

Manufactured by: Taro Pharmaceuticals Inc., Brampton, Ontario, Canada L6T 1C1

Distributed by: **Taro Pharmaceuticals U.S.A., Inc.**, Hawthorne, NY 10532

For more information, call 1-866-923-4914.

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

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