

## WARNINGS AND PRECAUTIONS

### 1 INDICATIONS AND USAGE

- **Dose:** this product is intended for use as a treatment of osteoarthritis of joints amenable to topical therapy. The proper amount of Diclofenac sodium topical gel is applied to the painful part of the joint(s). Do not apply the gel to treated joints.

### 2 DOSAGE AND ADMINISTRATION

- **How to use:** in the setting of coronary artery bypass graft (CABG) surgery in patients treated with diclofenac, the lowest effective dose should be used for the shortest duration possible. Physicians and patients should remain alert for the development of such events.

### 3 DOSAGE FORM AND STRENGTH

- **1% gel:** 5 g, 10 g, 20 g

### 4 CONTRAINDICATIONS

- **Diclofenac sodium topical gel is contraindicated in patients with:**
  - **known hypersensitivity to diclofenac.
  - **known sensitivity to aspirin or other NSAIDs.
  - **known sensitivity to any component of the formulation.

### 5 WARNINGS AND PRECAUTIONS

- **Cardiovascular and Gastrointestinal Risk:**
  - **Serious cardiovascular (CV) and gastrointestinal adverse events (including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal) may occur at any time, with any NSAID.**
  - **NSAIDs cause an increased risk of serious cardiovascular adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal.**
  - **These events can occur at any time, with any NSAID, but the risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.**
  - **Diclofenac sodium topical gel is contraindicated in the treatment of post- operative pain in the setting of coronary artery bypass graft (CABG) surgery.**

### 6 ADVERSE REACTIONS

- **Local:** rash, pruritus, urticaria, or hives; local skin reaction; contact dermatitis; more frequent and/or more severe than with placebo.

### 7 DRUG INTERACTIONS

- **Serious and potentially fatal cardiovascular events, myocardial infarction, and stroke can occur with use of NSAIDs, including diclofenac sodium topical gel.**

### 8.2 Labor and Delivery

- **Diclofenac sodium topical gel should be used in patients with known CV disease or risk factors for CV disease.**

### 10 OVERDOSAGE

- **In patients with fluid retention or heart failure:** use with caution in patients at greatest risk.

### 12.2 Pharmacodynamics

- **The proper amount of diclofenac sodium topical gel should be used for treating the pain of osteoarthritis of joints amenable to topical therapy.**

### 13 CLINICAL STUDIES

- **Several studies that have been conducted to evaluate the safety and efficacy of diclofenac sodium topical gel.**

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### 15 FULL PRESCRIBING INFORMATION

- **For specified indications:**
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    - **Serious and potentially fatal cardiovascular events, myocardial infarction, and stroke can occur with use of NSAIDs, including diclofenac sodium topical gel.**
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### 20 DOSAGE AND ADMINISTRATION

- **The dosing card can be found attached to the tube of the product.**

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### 30 WARNING: CARDIOVASCULAR AND GASTROINTESTINAL RISK

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    - **Diclofenac sodium topical gel is contraindicated in the treatment of post-operative pain in the setting of coronary artery bypass graft (CABG) surgery.**
Monitoring of the patient’s renal function is advisable. Studies regarding the use of diclofenac sodium topical gel for the treatment of osteoarthritis of the knee have shown no evidence of an increase in the frequency of renal insufficiency. Patients receiving diclofenac sodium topical gel should be monitored for signs of reduced renal function, especially in patients with a history of renal disease, heart failure, or dehydration. Sodium retention and edema have been observed in some patients. In these patients, fluid retention and edema may lead to exacerbation of congestive heart failure, which may be complicated by hypovolemia, hypotension, and myocardial ischemia. Patients with congestive heart failure may tolerate NSAIDs more readily than other types of patients, but they may be more sensitive to decompensation of congestive heart failure, sodium retention, and edema. Some patients receiving therapy for congestive heart failure may develop symptoms of fluid retention and edema during using diclofenac sodium topical gel. Fluid retention and edema are more common among the elderly. Assess the patient’s hydration status and renal function. Inform the patient of proper hydration habits to minimize fluid retention and edema.

5.15 Eye Exposure
Contact of diclofenac sodium topical gel with the eyes should be avoided. Patients should be advised to wash out the eye with water if contact should occur. Contact of topical NSAIDs with eyes has not been associated with the induction of skin tumors. The potential effects of diclofenac sodium topical gel on the conjunctiva or cornea have not been studied. If eye irritation occurs with the use of diclofenac sodium topical gel, the eye should be washed out with water. Thereafter, if irritation persists, the patient should be referred to a qualified ophthalmologist for appropriate management. When treating the conjunctiva or cornea, no erosions, erosions, or ulcerations should be apparent. The application of topical NSAIDs to the eye and conjunctiva may cause conjunctivitis, ocular irritation, and mild pain. Patients should be advised to wash out the eye with water if contact should occur. If the eye becomes painful, it should be evaluated by an ophthalmologist.

5.12 Hematologic Effects
Anemia is sometimes seen in patients receiving NSAIDs. Anemia can be associated with the dose of NSAIDs. This may be due to fluid retention, occult or symptomatic gastrointestinal bleeding, or decreased production of red blood cells. The incidence of anemia is dose-related and is more common with higher dosages of NSAIDs. Diclofenac sodium topical gel is often used in a lower dosage range than oral NSAIDs. Anemia is rare except in the presence of severe renal insufficiency. Abrupt discontinuation of corticosteroids may lead to an exacerbation of anemia in patients with renal insufficiency. The dose of corticosteroids should be tapered slowly and monitored in patients with renal insufficiency. Patients with severe renal insufficiency should not receive corticosteroids.

5.13 Preexisting Asthma
Patients who have a history of aspirin-sensitive asthma may be at increased risk of adverse respiratory reactions when they receive diclofenac sodium topical gel. Published reports have indicated that patients who are aspirin-sensitive may experience serious respiratory reactions with the use of NSAIDs. Patients with aspirin-sensitive asthma may be at increased risk of adverse respiratory reactions when they receive diclofenac sodium topical gel. There is no published experience with diclofenac sodium topical gel in the treatment of patients with asthma. Patients who have a history of aspirin-sensitive asthma should be warned of the possibility of adverse respiratory reactions. The use of diclofenac sodium topical gel in patients with a history of aspirin-sensitive asthma should be approached with caution.

In the placebo-controlled trials, the discontinuation rate due to adverse events was 0% for patients treated with diclofenac sodium topical gel. Adverse events that led to the discontinuation of the study drug were reported in 5% of patients treated with diclofenac sodium topical gel. Adverse reactions that led to the discontinuation of the study drug were reported in 1% of patients treated with diclofenac sodium topical gel. Diclofenac, like other NSAIDs, may affect renal prostaglandin synthesis, which may be beneficial or detrimental depending on the patient’s medical condition. Diclofenac, like other NSAIDs, may affect renal prostaglandin synthesis, which may be beneficial or detrimental depending on the patient’s medical condition.

6.1 Clinical Trials Experience
Because clinical trials are conducted under highly controlled conditions, adverse reactions observed in the clinical trials may not reflect the adverse reaction rates observed in practice. Because many drugs are excreted in human milk and because studies in animals have not been done to study whether diclofenac in the milk after oral administration. Therefore, diclofenac is not recommended for use in pregnant women as it is not known whether it will cause fetal harm when administered to pregnant women. The use of diclofenac sodium topical gel during pregnancy may cause premature closure of the ductus arteriosus.

Teratogenic Effects
In rat studies with oral NSAIDs, including diclofenac, there has been no evidence of teratogenicity. In studies with oral NSAIDs, there is no evidence of teratogenicity in rat studies with oral NSAIDs. Therefore,Diclofenac sodium topical gel should be avoided because of the potential to alter local prostaglandin synthesis and body surface area compliance.

6.3 Neonatal Abstinence Syndrome
Neonatal abstinence syndrome has not been observed in infants born to women treated with NSAIDs, including diclofenac. Neonatal abstinence syndrome has not been observed in infants born to women treated with diclofenac. Therefore, diclofenac sodium topical gel should be avoided because of the potential to alter local prostaglandin synthesis and body surface area compliance.

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10 OVERDOSAGE

There has been experience of overdose with diclofenac sodium topical gel.

Events of a non-lethal nature have been reported with diclofenac sodium topical gel. Effects similar to those observed after oral overdose of diclofenac sodium can be expected. If sufficient amounts of diclofenac sodium topical gel are taken, signs and symptoms of systemic toxicity may be evident. Signs of systemic acute and NSAID overdose are usually related to symptoms, which can be expected if substantial amounts of diclofenac sodium topical gel are taken. Such symptoms may include nausea, vomiting, diarrhea, dizziness, headache, confusion, and epigastric pain, which are generally reversible with supportive care. Gastrointestinal bleeding may occur. Acute renal failure, respiratory depression, and coma may occur. Anaphylactic reactions have been reported. Supportive care, including intravenous fluids and respiratory support, is the usual treatment of overdosage, if needed or expected. If severe, oropharyngeal aspiration should be prevented by the placement of a nasogastric tube. Gastrointestinal decontamination may be useful to monitor renal function.

Because elderly patients are more likely to have decreased renal function, care should be taken when initiating therapy with diclofenac sodium topical gel. In elderly patients with liver and kidney disease, care should be taken when initiating therapy with diclofenac sodium topical gel, especially when increasing the dose to the usual amount. Elderly patients may be more sensitive than younger subjects, but greater sensitivity or safety were observed between these groups. The pharmacokinetics of diclofenac sodium were not significantly different between the two groups.

10.4 Special Populations

10.4.1 Geriatric Use

Clinical studies of diclofenac sodium topical gel did not include sufficient numbers of subjects aged 65 and over to establish whether they respond differently from younger subjects. In general, elderly patients tend to have decreased renal function, which may require dose adjustment.

1.4.2 Drug Interactions

Patients should be advised that diclofenac sodium topical gel is non-steroidal anti-inflammatory drug (NSAID) of the non-selective cyclooxygenase (COX) type.

Instruct patients to avoid contact of diclofenac sodium topical gel with the eyes or mucous membranes. If diclofenac sodium topical gel contacts the eyes, patients should wash the affected eye(s) with running water for at least 15 minutes. Instruct patients to immediately wash the eye(s) with copious amounts of saline solution.

Instruct patients to avoid concomitant use of diclofenac sodium topical gel with other NSAIDs or with COX-2 inhibitors. Instruct patients to avoid concomitant use of diclofenac sodium topical gel and other anticoagulants. The risk of serious skin reactions may be increased with the concurrent use of other systemic or topical corticosteroids. Instruct patients to avoid concomitant use of diclofenac sodium topical gel and other drugs that impair serotonin function such as selective serotonin reuptake inhibitors (SSRIs).

11 CLINICAL STUDIES

11.1 Overdose Studies

11.1.1 Pharmacokinetics

Following oral administration of diclofenac sodium, plasma concentration-time curves are similar to those observed after topical administration. The average peak plasma concentration with systemic exposure with recommended use of diclofenac sodium topical gel is 14 (0-24) ng/mL. The pharmacokinetics of diclofenac sodium topical gel were not significantly different between the two groups. The pharmacokinetics of diclofenac sodium topical gel were not significantly different between the two groups.

11.2 Pharmacokinetics

11.2.1 Pharmacodynamics

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11.3 Nonclinical Toxicology

11.3.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity studies in rats and mice administered oral diclofenac sodium for 2 years at doses of up to 150 mg/kg/day showed no evidence of carcinogenic potential in either species. In the rat, a statistically significant increase in the incidence of neoplastic foci of fibrosarcoma were found in both animals. However, the type of neoplasms were not found to be related to the route of administration. Therefore, concurrent use of diclofenac sodium topical gel is not recommended.

11.3.2 Impairment of Fertility

In a study conducted under identical conditions to those described in the 14.1.1 pharmacokinetics study, significant increases in litter size and/or neonatal survival were observed at doses of up to 150 mg/kg/day in one of the 2 rat strains and in the mouse. These findings were confirmed in the male fertility study, in both species. The findings may be due to the ability of diclofenac sodium to impair sperm motility and spermatogenesis in the male rat.

11.3.3 Local Tolerance

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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 have 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 breast-feeding. Talk to your healthcare provider.

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

Serious side effects include:

- heart attack
- stroke
- high blood pressure
- heart failure from body swelling (fluid retention)
- kidney problems including kidney failure
- blood clotting problems in the stomach and intestine
- low red blood cells (anemia)
- life-threatening skin reactions
- life-threatening allergic reactions

Other side effects include:

- stomach pain
- constipation
- diarrhea
- gas
- heartburn
- nausea
- vomiting
- dizziness

Other side effects include:

- liver problems including liver failure
- asthma attacks in people who have asthma

Get emergency help right away if you have any of the following symptoms:

- slurred speech
- 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

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

- Celecoxib
- Diclofenac
- Ibuprofen
- Ketoprofen
- Naproxen
- Indomethacin
- Indocin® SR
- Indocin®
- Ketoprofen
- Ketorolac
- Meloxicam
- Nabumetone
- Celebrex®
- Flector®, Cataflam®, Cambia®, Voltaren®, Voltaren® GEL, Arthrotec® (combined with misoprostol), Pennsaid®, Zipsor®, Zornox®
- Dolobid®
- Lodine®, Lodine® XL
- Motrin®, Tab-Profen®, Vicoprofen® (combined with hydrocodone), Combunox® (combined with oxycodone), Duese® (combined with famotidine)
- Indocin®, Indocin® SR, Indo-Lemmon®, Indomethagan®
- Duofal®, Niacide®
- Toradol®, Sprix®
- Mefenamic Acid
- Penstrel®
- Mobic®
- Relafen®

Guide for a list of prescription NSAID medicines. (NSAIDs)
prescribed diclofenac sodium

Your healthcare provider has the place of talking to your pharmacist 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.

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 1-800-398-5876. 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.

Step 2. Squeeze the diclofenac sodium topical gel onto the dosing card evener, 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.

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, polyoxy 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.

Distributed by: Par Pharmaceutical
Chestnut Ridge, NY 10977

Manufactured by: Novartis Pharma Produktions GmbH
Wehr, Germany

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Figure E

Figure F

Figure G