

TORVEX- diclofenac sodium and menthol, methyl salicylate Florrx Pharmaceutical

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

HIGHLIGHTS OF PRESCRIBING INFORMATION

Torvex: These highlights do not include all the information needed to use DICLOFENAC SODIUM TOPICAL SOLUTION safely and effectively. See full prescribing information for DICLOFENAC SODIUM TOPICAL SOLUTION.

**DICLOFENAC SODIUM topical solution 1.5% w/w, for topical use
Initial U.S. Approval: 1988**

WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS

See full prescribing information for complete boxed warning.

- **Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use. (5.1)**
- **Diclofenac sodium topical solution is contraindicated in the setting of coronary artery bypass graft (CABG) surgery. (4,5.1)**
- **NSAIDs, cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and or GI bleeding are at greater risk for serious GI events. (5.2)**

INDICATIONS AND USAGE

Diclofenac sodium topical solution is a nonsteroidal anti-inflammatory drug indicated for the treatment of signs and symptoms of osteoarthritis of the knee(s). (1)

DOSAGE FORMS AND STRENGTHS

Diclofenac sodium topical solution 1.5% w/w (3)

CONTRAINDICATIONS

- Known hypersensitivity to diclofenac or any components of the drug product. (4)
- History of asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. (4)
- In the setting of CABG surgery. (4)

ADVERSE REACTIONS

Most common adverse reactions with diclofenac sodium topical solution are application site reactions. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Amneal Pharmaceuticals at 1-877-835-5472 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- **Drugs that Interfere with Hemostasis (e.g., warfarin, aspirin, SSRIs/SNRIs):** Monitor patients for bleeding who are concomitantly using diclofenac sodium topical solution with drugs that interfere with hemostasis. Concomitant use of diclofenac sodium topical solution and analgesic doses of aspirin is not generally recommended. (7)
- **ACE Inhibitors, Angiotensin Receptor Blockers (ARB), or Beta-Blockers:** Concomitant use with diclofenac sodium topical solution may diminish the antihypertensive effect of these drugs. Monitor blood pressure. (7)
- **ACE Inhibitors and ARBs:** Concomitant use with diclofenac sodium topical solution in elderly, volume depleted, or those with renal impairment may result in deterioration of renal function. In such high risk patients, monitor for signs of worsening renal function. (7)
- **Diuretics:** NSAIDs can reduce natriuretic effect of furosemide and thiazide diuretics. Monitor patients to assure diuretic efficacy including antihypertensive effects. (7)

- Digoxin: Concomitant use with diclofenac sodium topical solution can increase serum concentration and prolong half-life of digoxin. Monitor serum digoxin levels. (7)

See 17 for **PATIENT COUNSELING INFORMATION** and **Medication Guide**.

Revised: 7/2025

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FULL PRESCRIBING INFORMATION

WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS

Cardiovascular Thrombotic Events

- **Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use [see Warnings and Precautions (5.1)].**
- **Diclofenac sodium topical solution is contraindicated in the setting of coronary artery bypass graft (CABG) surgery [see Contraindications (4) and Warnings and Precautions (5.1)].**

Gastrointestinal Bleeding, Ulceration, and Perforation

- **NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and or GI bleeding are at greater risk for serious GI events [see Warnings and Precautions (5.2)].**

1 INDICATIONS AND USAGE

Diclofenac sodium topical solution is indicated for the treatment of signs and symptoms of osteoarthritis of the knee(s).

3 DOSAGE FORMS AND STRENGTHS

Diclofenac sodium topical solution: 1.5% w/w

4 CONTRAINDICATIONS

Diclofenac sodium topical solution is contraindicated in the following patients:

- Known hypersensitivity (e.g., anaphylactic reactions and serious skin reactions) to diclofenac or any components of the drug product [see Warnings and Precautions (5.7,5.9)].
- History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. Severe, sometimes fatal, anaphylactic reactions to NSAIDs have been reported in such patients [see Warnings and Precautions (5.7,5.8)].
- In the setting of coronary artery bypass graft (CABG) surgery [see Warnings and Precautions (5.1)].

6 ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the labeling:

- Cardiovascular Thrombotic Events [see Warnings and Precautions (5.1)]
- GI Bleeding, Ulceration and Perforation [see Warnings and Precautions (5.2)]
- Hepatotoxicity [see Warnings and Precautions (5.3)]
- Hypertension [see Warnings and Precautions (5.4)]
- Heart Failure and Edema [see Warnings and Precautions (5.5)]
- Renal Toxicity and Hyperkalemia [see Warnings and Precautions (5.6)]
- Anaphylactic Reactions [see Warnings and Precautions (5.7)]
- Serious Skin Reactions [see Warnings and Precautions (5.9)]
- Hematologic Toxicity [see Warnings and Precautions (5.12)]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The data described below reflect exposure to diclofenac sodium topical solution of 911 patients treated between 4 and 12 weeks (mean duration of 49 days) in seven Phase 3 controlled trials, as well as exposure of 793 patients treated in an open-label study, including 463 patients treated for at least 6 months, and 144 patients treated for at least 12 months. The population mean age was approximately 60 years, 89% of patients were Caucasians, 64% were females, and all patients had primary osteoarthritis. The most common adverse events with diclofenac sodium topical solution were application site skin reactions. These events were the most common reason for withdrawing from the studies.

Application Site Reactions

In controlled trials, the most common treatment-related adverse events in patients receiving diclofenac sodium topical solution were application site skin reactions. Application site reactions were characterized by one or more of the following: dryness, erythema, induration, vesicles, paresthesia, pruritus, vasodilation, acne, and urticaria. The most frequent of these reactions were dry skin (32%), contact dermatitis characterized by skin erythema and induration (9%), contact dermatitis with vesicles (2%) and pruritus (4%). In one controlled trial, a higher rate of contact dermatitis with vesicles (4%) was observed after treatment of 152 subjects with the combination of diclofenac sodium topical solution and oral diclofenac. In the open label uncontrolled long-term safety study, contact dermatitis occurred in 13% and contact dermatitis with vesicles in 10% of patients, generally within the first 6 months of exposure, leading to a withdrawal rate for an application site event of 14%.

Adverse Events Common to the NSAID Class

In controlled trials, subjects treated with diclofenac sodium topical solution experienced some adverse events associated with the NSAID class more frequently than subjects using placebo (constipation, diarrhea, dyspepsia, nausea, flatulence, abdominal pain, edema; see **Table 1**). The combination of diclofenac sodium topical solution and oral diclofenac, compared to oral diclofenac alone, resulted in a higher rate of rectal hemorrhage (3% vs. less than 1%), and more frequent abnormal creatinine (12% vs. 7%), urea (20% vs. 12%), and hemoglobin (13% vs. 9%), but no difference in elevation of liver transaminases.

Table 1 lists all adverse reactions occurring in $\geq 1\%$ of patients receiving diclofenac

sodium topical solution, where the rate in the diclofenac sodium topical solution group exceeded placebo, from seven controlled studies conducted in patients with osteoarthritis. Since these trials were of different durations, these percentages do not capture cumulative rates of occurrence.

Table 1: Adverse Reactions occurring in $\geq 1\%$ of patients treated with diclofenac sodium topical solution in placebo and oral diclofenac-controlled trials.

Treatment Group:	Diclofenac sodium topical solution N=911	Topical Placebo N=332
Adverse Reaction†	N (%)	N (%)
Dry Skin (Application Site)	292 (32)	17 (5)
Contact Dermatitis (Application Site)	83 (9)	6 (2)
Dyspepsia	72 (8)	13 (4)
Abdominal Pain	54 (6)	10 (3)
Flatulence	35 (4)	1 (<1)
Pruritus (Application Site)	34 (4)	7 (2)
Diarrhea	33 (4)	7 (2)
Nausea	33 (4)	3 (1)
Pharyngitis	40 (4)	13 (4)
Constipation	29 (3)	1 (<1)
Edema	26 (3)	0
Rash (Non-Application Site)	25 (3)	5 (2)
Infection	25 (3)	8 (2)
Ecchymosis	19 (2)	1 (<1)
Dry Skin (Non-Application Site)	19 (2)	1 (<1)
Contact Dermatitis, vesicles (Application	18 (2)	0

Site)		
Paresthesia (Non-Application Site)	14 (2)	3 (<1)
Accidental Injury	22 (2)	7 (2)
Pruritus (Non-Application Site)	15 (2)	2 (<1)
Sinusitis	10 (1)	2 (<1)
Halitosis	11 (1)	1 (<1)
Application Site Reaction (not otherwise specified)	11 (1)	3 (<1)
†Preferred Term according to COSTART		

6.2 Postmarketing Experience

In non-U.S. postmarketing surveillance, the following adverse reactions have been reported during post-approval use of diclofenac sodium topical solution. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Body as a Whole: abdominal pain, accidental injury, allergic reaction, asthenia, back pain, body odor, chest pain, edema, face edema, halitosis, headache, lack of drug effect, neck rigidity, pain

Cardiovascular: palpitation, cardiovascular disorder

Digestive: diarrhea, dry mouth, dyspepsia, gastroenteritis, decreased appetite, mouth ulceration, nausea, rectal hemorrhage, ulcerative stomatitis

Metabolic and Nutritional: creatinine increased

Musculoskeletal: leg cramps, myalgia

Nervous: depression, dizziness, drowsiness, lethargy, paresthesia, paresthesia at application site

Respiratory: asthma, dyspnea, laryngismus, laryngitis, pharyngitis

Skin and Appendages: *At the Application Site:* Adverse Reactions: contact dermatitis, contact dermatitis with vesicles, dry skin, pruritus, rash; *Other Skin and Appendages:* eczema, rash, pruritus, skin discoloration, urticaria

Special Senses: abnormal vision, blurred vision, cataract, ear pain, eye disorder, eye pain, taste perversion

7 DRUG INTERACTIONS

See Table 2 for clinically significant drug interactions with diclofenac.

Table 2: Clinically Significant Drug Interactions with Diclofenac

Drugs That Interfere with Hemostasis	
<i>Clinical Impact:</i>	<ul style="list-style-type: none"> • Diclofenac and anticoagulants such as warfarin have a synergistic effect on bleeding. The concomitant use of diclofenac and anticoagulants have an increased risk of serious bleeding compared to the use of either drug alone. • Serotonin release by platelets plays an important role in hemostasis. Case-control and cohort epidemiological studies showed that concomitant use of drugs that interfere with serotonin reuptake and an NSAID may potentiate the risk of bleeding more than an NSAID alone.
<i>Intervention:</i>	Monitor patients with concomitant use of diclofenac sodium topical solution with anticoagulants (e.g., warfarin), antiplatelet agents (e.g., aspirin), selective serotonin reuptake inhibitors (SSRIs), and serotonin norepinephrine reuptake inhibitors (SNRIs) for signs of bleeding [see <i>Warnings and Precautions (5.12)</i>]
Aspirin	
<i>Clinical Impact:</i>	Controlled clinical studies showed that the concomitant use of NSAIDs and analgesic doses of aspirin does not produce any greater therapeutic effect than the use of NSAIDs alone. In a clinical study, the concomitant use of an NSAID and aspirin was associated with a significantly increased incidence of GI adverse reactions as compared to use of NSAID alone [see <i>Warnings and Precautions (5.2)</i>]
<i>Intervention:</i>	Concomitant use of diclofenac sodium topical solution and analgesic doses of aspirin is not generally recommended because of the increased risk of bleeding [see <i>Warnings and Precautions (5.12)</i>]. Diclofenac sodium topical solution is not a substitute for low dose aspirin for cardiovascular protection.
ACE inhibitors, Angiotensin Receptor Blockers, and Beta-Blockers	
<i>Clinical Impact:</i>	<ul style="list-style-type: none"> • NSAIDs may diminish the antihypertensive effect of angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), or beta-blockers (including propranolol). • In patients who are elderly, volume-depleted (including those on diuretic therapy), or have renal impairment, co-administration of an NSAID with ACE inhibitors or ARBs may result in deterioration of renal function, including possible acute renal failure. These effects are usually reversible.
	<ul style="list-style-type: none"> • During concomitant use of diclofenac sodium topical solution and ACE-inhibitors, ARBs, or beta-blockers, monitor blood pressure to ensure that the desired blood pressure is obtained. • During concomitant use of diclofenac sodium topical solution and ACE-

<i>Intervention:</i>	<p>inhibitors or ARBs in patients who are elderly, volume-depleted, or have impaired renal function, monitor for signs of worsening renal function [see <i>Warnings and Precautions</i>(5.6)]</p> <ul style="list-style-type: none"> • When these drugs are administered concomitantly, patients should be adequately hydrated. Assess renal function at the beginning of the concomitant treatment and periodically thereafter.
Diuretics	
<i>Clinical Impact:</i>	Clinical studies, as well as post-marketing observations, showed that NSAIDs reduced the natriuretic effect of loop diuretics (e.g., furosemide) and thiazide diuretics in some patients. This effect has been attributed to the NSAID inhibition of renal prostaglandin synthesis.
<i>Intervention:</i>	During concomitant use of diclofenac sodium topical solution with diuretics, observe patients for signs of worsening renal function, in addition to assuring diuretic efficacy including antihypertensive effects [see <i>Warnings and Precautions</i> (5.6)].
Digoxin	
<i>Clinical Impact:</i>	The concomitant use of diclofenac with digoxin has been reported to increase the serum concentration and prolong the half-life digoxin.
<i>Intervention:</i>	During concomitant use of diclofenac sodium topical solution and digoxin, monitor serum digoxin levels.
Lithium	
<i>Clinical Impact:</i>	NSAIDs have produced elevations in plasma lithium levels and reductions in renal lithium clearance. The mean minimum lithium concentration increased 15%, and the renal clearance decreased by approximately 20%. This effect has been attributed to NSAID inhibition of renal prostaglandin synthesis.
<i>Intervention:</i>	During concomitant use of diclofenac sodium topical solution and lithium, monitor patients for signs of lithium toxicity.
Methotrexate	
<i>Clinical Impact:</i>	Concomitant use of NSAIDs and methotrexate may increase the risk of methotrexate toxicity (e.g., neutropenia, thrombocytopenia, renal dysfunction).
<i>Intervention:</i>	During concomitant use of diclofenac sodium topical solution and methotrexate, monitor patients for methotrexate toxicity.
Cyclosporine	
<i>Clinical Impact:</i>	Concomitant use of diclofenac sodium topical solution and cyclosporine may increase cyclosporine's nephrotoxicity.
<i>Intervention:</i>	During concomitant use of diclofenac sodium topical solution and cyclosporine, monitor patients for signs or worsening renal function.
NSAIDs and Salicylates	
<i>Clinical Impact:</i>	Concomitant use of diclofenac with other NSAIDs or salicylates (e.g., diflunisal, salsalate) increases the risk of GI toxicity, with little or no increase in efficacy [see <i>Warnings and Precautions</i> (5.2)]. Concomitant use of oral NSAIDs with diclofenac sodium topical solution has been evaluated in one Phase 3 controlled trial and in combination with oral diclofenac, compared to oral diclofenac alone, resulted in a higher rate of rectal hemorrhage (3% vs. less than 1%), and more frequent abnormal creatinine (12% vs. 7%), urea (20% vs. 12%) and hemoglobin (13% vs. 9%).

<i>Intervention:</i>	The concomitant use of diclofenac with other NSAIDs or salicyclates is not recommended. Do not use combination therapy with diclofenac sodium topical solution and an oral NSAID unless the benefit outweighs the risk and conduct periodic laboratory evaluations
Pemetrexed	
<i>Clinical Impact:</i>	Concomitant use of diclofenac sodium topical solution and pemetrexed may increase the risk of pemetrexed-associated myelosuppression, renal, and GI toxicity (see the pemetrexed prescribing information).
<i>Intervention:</i>	During concomitant use of diclofenac sodium topical solution and pemetrexed, in patients with renal impairment whose creatinine clearance ranges from 45 to 79 mL/min, monitor for myelosuppression, renal and GI toxicity. NSAIDs with short elimination half-lives (e.g., diclofenac, indomethacin) should be avoided for a period of two days before, the day of, and two days following administration pemetrexed. In the absence of data regarding potential interaction between pemetrexed and NSAIDs with longer half-lives (e.g., meloxicam, nabumetone), patients taking these NSAIDs should interrupt dosing for at least five days before, the day of, and two days following pemetrexed administration.

10 OVERDOSAGE

Symptoms following acute NSAID overdosages have been typically limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which have been generally reversible with supportive care. Gastrointestinal bleeding has occurred. Hypertension, acute renal failure, respiratory depression, and coma have occurred, but were rare [see *Warnings and Precautions (5.1,5.2,5.4,5.6)*].

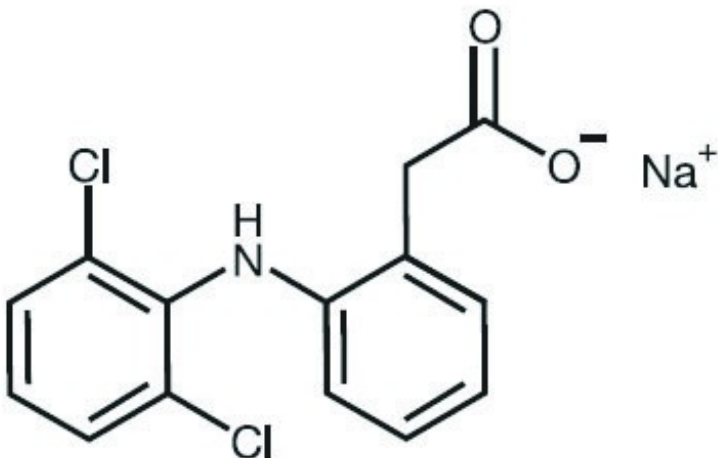
Manage patients with symptomatic and supportive care following an NSAID overdose. There are no specific antidotes. Emesis is not recommended due to a possibility of aspiration and subsequent respiratory irritation by DMSO contained in diclofenac sodium topical solution. Consider activated charcoal (60 to 100 grams in adults, 1 to 2 grams per kg of body weight in pediatric patients) and/or osmotic cathartic in symptomatic patients seen within four hours of ingestion or in patients with a large overdose (5 to 10 times the recommended dosage). Forced diuresis, alkalinization of urine, hemodialysis, or hemoperfusion may not be useful due to high protein binding. For additional information about overdose treatment, contact a poison control center (1-800-222-1222).

11 DESCRIPTION

Diclofenac sodium topical solution 1.5% is a nonsteroidal anti-inflammatory drug, available as a clear, colorless to faintly pink-orange solution for topical application.

Diclofenac sodium topical solution contains 1.5% w/w diclofenac sodium, USP, a benzeneacetic acid derivative that is a nonsteroidal anti-inflammatory drug (NSAID), designated chemically as 2-[(2,6-dichlorophenyl)amino]-benzeneacetic acid, monosodium salt. It is a white to off-white crystalline powder, hygroscopic, and odorless that is freely soluble in methanol, soluble in alcohol, and sparingly soluble in water. The molecular weight is 318.13. Its molecular formula is $C_{14}H_{10}Cl_2NNaO_2$ and it has the

following structural formula.



Each 1 mL of solution contains 16.05 mg of diclofenac sodium, USP. The inactive ingredients in diclofenac sodium topical solution include: alcohol, dimethyl sulfoxide USP (DMSO, 45.5% w/w), glycerin, propylene glycol, and purified water.

16 HOW SUPPLIED/STORAGE AND HANDLING

Diclofenac sodium topical solution **1.5%** w/w is supplied as a clear, colorless to faintly pink-orange solution containing 16.05 mg of diclofenac sodium per 1 mL of solution, in a white high density polyethylene bottle with a white low-density dropper cap. It is available as follows:

150 mL bottle NDC 65162-911-74

Storage

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide) and Instructions for Use that accompanies each prescription dispensed. Inform patients, families, or their caregivers of the following information before initiating therapy with diclofenac sodium topical solution and periodically during the course of ongoing therapy.

Cardiovascular Thrombotic Events

Advise patients to be alert for the symptoms of cardiovascular thrombotic events, including chest pain, shortness of breath, weakness, or slurring of speech, and to report any of these symptoms to their health care provider immediately [see *Warnings and Precautions* (5.1)].

Gastrointestinal Bleeding, Ulceration, and Perforation

Advise patients to report symptoms of ulcerations and bleeding, including epigastric pain, dyspepsia, melena, and hematemesis to their health care provider. In the setting of concomitant use of low-dose aspirin for cardiac prophylaxis, inform patients of the increased risk for and the signs and symptoms of GI bleeding [see *Warnings and Precautions (5.2)*].

Hepatotoxicity

Inform patients of the warning signs and symptoms of hepatotoxicity (e.g., nausea, fatigue, lethargy, pruritus, diarrhea, jaundice, right upper quadrant tenderness, and “flu-like” symptoms). If these occur, instruct patients to stop diclofenac sodium topical solution and seek immediate medical therapy [see *Warnings and Precautions (5.3)*].

Heart Failure and Edema

Advise patients to be alert for the symptoms of congestive heart failure including shortness of breath, unexplained weight gain, or edema and to contact their healthcare provider if such symptoms occur [see *Warnings and Precautions (5.5)*].

Anaphylactic Reactions

Inform patients of the signs of an anaphylactic reaction (e.g., difficulty breathing, swelling of the face or throat). Instruct patients to seek immediate emergency help if these occur [see *Contraindications (4)* and *Warnings and Precautions (5.7)*].

Serious Skin Reactions, including DRESS

Advise patients to stop taking diclofenac sodium topical solution immediately if they develop any type of rash or fever and to contact their healthcare provider as soon as possible [see *Warnings and Precautions (5.9, 5.10)*].

Female Fertility

Advise females of reproductive potential who desire pregnancy that NSAIDs, including diclofenac sodium topical solution, may be associated with a reversible delay in ovulation [see *Use in Specific Populations (8.3)*].

Fetal Toxicity

Inform pregnant women to avoid use of diclofenac sodium topical solution and other NSAIDs starting at 30 weeks gestation because of the risk of the premature closing of the fetal ductus arteriosus. If treatment with diclofenac sodium topical solution is needed for a pregnant woman between about 20 to 30 weeks gestation, advise her that she may need to be monitored for oligohydramnios, if treatment continues for longer than 48 hours [see *Warnings and Precautions (5.11)* and *Use in Specific Populations (8.1)*].

Avoid Concomitant Use of NSAIDs

Inform patients that the concomitant use of diclofenac sodium topical solution with other NSAIDs or salicylates (e.g., diflunisal, salsalate) is not recommended due to the increased risk of gastrointestinal toxicity, and little or no increase in efficacy [see *Warnings and Precautions (5.2)* and *Drug Interactions (7)*]. Alert patients that NSAIDs may be present in “over the counter” medications for treatment of colds, fever, or insomnia.

Use of NSAIDs and Low-Dose Aspirin

Inform patients not to use low-dose aspirin concomitantly with diclofenac sodium topical solution until they talk to their healthcare provider [see *Drug Interactions (7)*].

Eye Exposure

Instruct patients to avoid contact of diclofenac sodium topical solution with the eyes and mucosa. Advise patients that if eye contact occurs, immediately wash out the eye with water or saline and consult a physician if irritation persists for more than an hour.

Prevention of Secondary Exposure

Instruct patients to avoid skin-to-skin contact between other people and the knee(s) to which diclofenac sodium topical solution was applied until the knee(s) is completely dry.

Application Site Reactions

Diclofenac sodium topical solution can cause a localized skin reaction at the application site. Advise patients to contact their physicians as soon as possible if they develop any type of localized application site rash.

Special Application Instructions

- Instruct patients not to apply diclofenac sodium topical solution to open skin wounds, infections, inflammations, or exfoliative dermatitis, as it may affect absorption and reduce tolerability of the drug.
- Instruct patients to wait until the area treated with diclofenac sodium topical solution is completely dry before applying sunscreen, insect repellent, lotion, moisturizer, cosmetics, or other topical medication.
- Instruct patients to minimize or avoid exposure of treated knee(s) to natural or artificial sunlight.

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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 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. Taking NSAIDs at about 20 weeks of pregnancy or later may harm your unborn baby. If you need to take NSAIDs for more than 2 days when you are between 20 and 30 weeks of pregnancy, your healthcare provider may need to monitor the amount of fluid in your womb around your baby. **You should not take NSAIDs after about 30 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:

- 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 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

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 healthcare 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.

Distributed by:

Amneal Pharmaceuticals

Bridgewater, NJ 08807

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.

Revised 11-2020-02

Instructions for Use

Diclofenac (dye-KLOE-fen-ak) Sodium Topical Solution 1.5%

Read the Medication Guide that comes with diclofenac sodium topical solution first. Be sure that you read, understand and follow these Instructions for Use before you use diclofenac sodium topical solution for the first time.

Important: For use on the skin only (topical). Do not get diclofenac sodium topical solution in your eyes, nose or mouth.

Before you use diclofenac sodium topical solution:

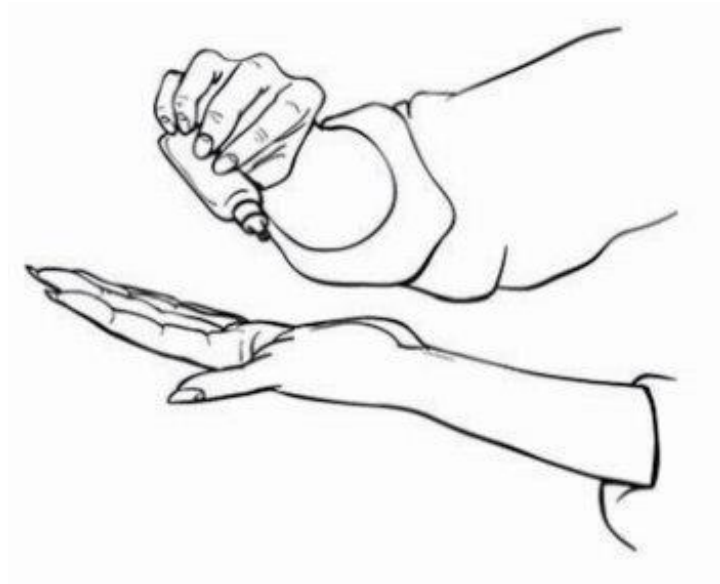
- Apply diclofenac sodium topical solution exactly as your healthcare provider tells you. Talk with your healthcare provider or pharmacist if you are not sure.
- Only use diclofenac sodium topical solution to treat pain from osteoarthritis in your knee or knees.
- Apply diclofenac sodium topical solution on clean, dry skin that does not have any cuts, infections or rashes.
- Use diclofenac sodium topical solution 4 times each day on your knee or knees as prescribed.
- Your total dose for each knee is 40 drops of diclofenac sodium topical solution, each time you use it.
- If you get diclofenac sodium topical solution in your eyes, rinse your eyes right away with water or saline. Call your healthcare provider if your eyes are irritated for more than one hour.

Steps for using diclofenac sodium topical solution:

Step 1. Wash your hands with soap and water before applying diclofenac sodium topical solution.

Step 2. Put 10 drops of diclofenac sodium topical solution **either** on your hand **or** directly on your knee (see **Figure A**).

Figure A



or



Step 3. Spread diclofenac sodium topical solution evenly on the front, back and sides of your knee (see **Figures B** and **C**). Repeat steps 2 and 3, three times so that your knee is completely covered with a **total** of 40 drops of diclofenac sodium topical solution.

Figure B

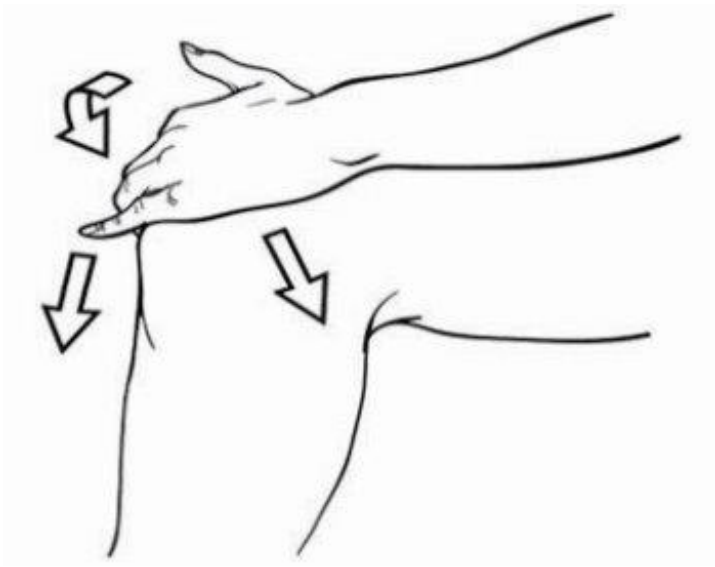
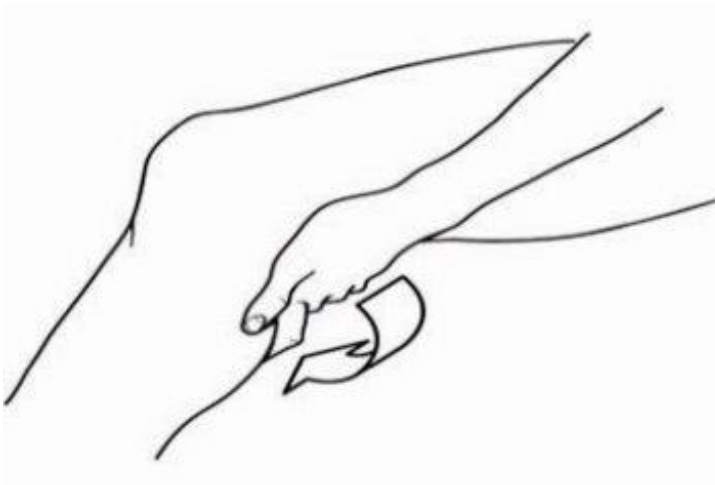


Figure C



Step 4. If your healthcare provider has prescribed diclofenac sodium topical solution for both knees, repeat steps 2 and 3 for the other knee.

After you use diclofenac sodium topical solution:

- Wash your hands with soap and water right away after applying diclofenac sodium topical solution.

Do not:

- touch the treated knee or allow another person to touch the knee treated with diclofenac sodium topical solution until your knee is completely dry.
- cover your knee with clothing until your knee is completely dry.
- put sunscreen, insect repellent, lotion, moisturizer, cosmetics, or other topical medicines on your knee until it is completely dry.
- take a shower or a bath for at least 30 minutes after you put diclofenac sodium topical solution on your knee.

- use heating pads or cover the treated area with bandages where you have applied diclofenac sodium topical solution.
- use sunlamps and tanning beds. Protect your treated knee from sunlight. Wear clothes that cover your skin if you have to be in sunlight.

How should I store diclofenac sodium topical solution?

- Store diclofenac sodium topical solution at room temperature between 68°F to 77°F (20°C to 25°C).

Keep diclofenac sodium topical solution and all medicines out of the reach of children.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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Distributed by:

Amneal Pharmaceuticals Bridgewater, NJ 08807

Rev. 11-2016-01

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



NDC 65162-911-74

Diclofenac Sodium Topical Solution, 1.5% w/w

Apply diclofenac sodium topical solution to clean, dry skin. Allow several minutes for diclofenac sodium topical solution to dry. Avoid skin-to-skin contact between other people and the treated knee(s) until completely dry. **After application, wash the hands.** See package insert for complete prescribing information.

Avoid contact with the eyes or mucous membranes.

WARNING: If persistent skin irritation develops, discontinue use of product and consult your physician.

FOR EXTERNAL USE ONLY

Excipients: alcohol (11.79%), dimethyl sulfoxide, USP, glycerin, propylene glycol and purified water.

Usual dosage:

40 drops to a knee, four times a day.

Storage: Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Dispense Enclosed Medication Guide To Each Patient.

Each mL contains: Active Ingredient:
diclofenac sodium, USP, 16.05 mg.

Rev. 05-2016-00

LOT

EXP

Rx only

Net Contents:
5 fl oz (150 mL)

Distributed by: **Amneal Pharmaceuticals**
Bridgewater, NJ 08807



**Diclofenac Sodium
Topical Solution,
1.5% w/w**
NDC 65162-911-74
FOR EXTERNAL USE ONLY

NDC 65162-911-74

**Diclofenac Sodium
Topical Solution,
1.5% w/w**

Avoid contact with the eyes or
mucous membranes.

FOR EXTERNAL USE ONLY

Usual dosage:
40 drops to a knee, four times a day.

**Dispense Enclosed Medication Guide to
Each Patient.**

Each mL contains: Active Ingredient:
diclofenac sodium, USP, 16.05 mg.

Rx only

Net Contents:
5 fl oz (150 mL)



Apply diclofenac sodium topical solution to clean, dry skin. Allow several minutes for diclofenac sodium topical solution to dry. Avoid skin-to-skin contact between other people and the treated knee(s) until completely dry. **After application, wash the hands.** See package insert for complete prescribing information.

WARNING: If persistent skin irritation develops, discontinue use of product and consult your physician.

Excipients:
alcohol (11.79%), dimethyl sulfoxide, USP, glycerin, propylene glycol and purified water.

Storage:
Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Rev. 05-2016-00

NDC 65162-911-74

**Diclofenac Sodium
Topical Solution,
1.5% w/w**

Avoid contact with the eyes or
mucous membranes.

FOR EXTERNAL USE ONLY



Rx only

Net Contents:
5 fl oz (150 mL)



LOT
EXP

Distributed by:
Amneal Pharmaceuticals
Bridgewater, NJ 08807

Muscle Rub

Menthol
Methyl Salicylate

Topical analgesic

Keep out of reach of children to avoid accidental ingestion. If swallowed, get medical help or contact a Poison Control Center Immediately.

For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, and sprains.

For external use only

Do not use:

On wounds or damaged skin

With a heating pad

On a child under 12 years of age with arthritis-like conditions

Ask a doctor before use if

you have redness over the affected area

When using this product

Avoid contact with eyes

Do not bandage tightly

Stop use and ask a doctor if

Condition worsens or symptoms persist for more than 7 days

Symptoms clear up and occur again within a few days

Excessive skin irritation occurs

Adults and children 12 years of age and older:

apply to affected area not more than 3 to 4 times daily

wash hands with soap and water after apply

Children under 12 years of age: ask a doctor

Citric Acid monohydrate, Glyceryl Monostearate, Lanolin, Methylparaben, Propylene Glycol, Propylparaben, Purified Water, Polysorbate 80, Stearic Acid, Trolamine



Muscle Rub

GREASELESS PAIN RELIEVING CREAM

NET WT. 3 OZ (85g)

Drug Facts		Drug Facts (continued)	
Active Ingredients	Purpose	Stop use and ask a doctor if	
Menthol 10%.....	Topical Analgesic	<ul style="list-style-type: none"> ■ excessive skin irritation occurs ■ condition worsens or symptoms persist for more than 7 days ■ symptoms clear up and occur again within a few days 	
Methyl Salicylate 15%	Topical Analgesic	Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center immediately.	
Uses		Directions	
For the temporary relief of minor aches and pains of muscles and joints associated with:		Adults 12 years of age and older:	
<ul style="list-style-type: none"> ■ simple backache ■ arthritis ■ strains ■ sprains ■ bruises 		<ul style="list-style-type: none"> ■ Apply to affected area not more than 3 to 4 times daily ■ Wash hands with soap and water after applying 	
Warnings		Children under 12 years of age: consult a doctor	
For external use only.		Other information ■ Store between 15° to 25°C (59° to 77°F)	
Do not use ■ on wounds or damaged skin ■ with a heating pad		■ Lot No. & Exp. Date: See box or crimp of tube	
■ on children under 12 years of age with arthritis-like conditions		Inactive Ingredients	
Ask a doctor before use if you have redness over the affected area		Citric Acid Monohydrate, Glyceryl Monostearate, Lanolin, Methylparaben, Propylene Glycol, Propylparaben, Purified Water, Polysorbate 80, Stearic Acid, Trolamine	
When using this product			
<ul style="list-style-type: none"> ■ avoid contact with eye ■ do not bandage tightly 			

Distributed by: CareALL Products, 160 Athens Way, Nashville, TN 37228 www.careallproducts.com KNW5146T-2 Made in India NDC # 51824-105-03

Torvex Packaging

The packaging for Torvex is shown below:



pdp

TORVEX

diclofenac sodium and menthol, methyl salicylate kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:84460-801
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Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:84460-801-01	1 in 1 CARTON; Type 0: Not a Combination Product	03/24/2026	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	150 mL
Part 2	1 TUBE	85 g

Part 1 of 2

DICLOFENAC SODIUM

diclofenac solution

Product Information

Item Code (Source)	NDC:65162-911
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Diclofenac Sodium (UNII: QTG126297Q) (Diclofenac - UNII:14408QL0L1)	Diclofenac Sodium	16.05 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Dimethyl Sulfoxide (UNII: YOW8V9698H)	
Glycerin (UNII: PDC6A3C0OX)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Alcohol (UNII: 3K9958V90M)	
Water (UNII: 059QF0KO0R)	

Product Characteristics

Color	white (clear to faintly pink-orange)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65162-911-74	1 in 1 CARTON		

1	150 mL in 1 BOTTLE; Type 0: Not a Combination Product		
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206116		

Part 2 of 2

CAREALL MUSCLE RUB ULTRA STRENGTH

menthol, methyl salicylate cream

Product Information

Item Code (Source)	NDC:51824-105
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEVOMENTHOL (UNII: BZ1R15MTK7) (LEVOMENTHOL - UNII:BZ1R15MTK7)	LEVOMENTHOL	100 mg in 1 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	150 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LANOLIN (UNII: 7EV65EAW6H)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Product Characteristics

Color	white (White)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51824-105-03	85 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/24/2026	

Labeler - Florrax Pharmaceutical (119257612)

Establishment

Name	Address	ID/FEI	Business Operations
Amneal Pharmaceuticals of New York, LLC		123797875	label(65162-911) , manufacture(65162-911)

Revised: 3/2026

Florrax Pharmaceutical