Introducing the first and only Rx topical NSAID specifically for OA pain*

(actual size)

*Voltaren® Gel is indicated for the relief of the pain of osteoarthritis (OA) of joints amenable to topical treatment, such as the knees and those of the hands. Voltaren Gel has not been evaluated for use on the spine, hip, or shoulder.

Please see accompanying full Prescribing Information for Warnings and Contraindications.

NEW

Voltaren® Gel (diclofenac sodium topical gel) 1%

Targeted NSAID Pain Relief With a Favorable Safety Profile

Voltaren® Gel (diclofenac sodium topical gel) 1%

- **NDC No.** 0067-6215-97
- **Supplied in 100 g tubes;** each tube contains diclofenac sodium in a gel base (10 mg of diclofenac sodium per gram of gel or 1%)
- Store Voltaren Gel at room temperature, 59° F to 86° F (15° C to 30° C)

Voltaren Gel is indicated for the relief of the pain of osteoarthritis of joints amenable to topical treatment, such as the knees and those of the hands. Voltaren Gel has not been evaluated for use on the spine, hip, or shoulder.

- Statistically significant improvement in OA knee and hand pain*[1-3]
  - 51% improvement from baseline in knee pain at Week 12 vs 39% with placebo (*P*=0.023); primary endpoint[2]
  - 42% improvement from baseline in hand pain at Week 4 vs 32% with placebo (*P*=0.018); 46% improvement from baseline at Week 6 vs 36% with placebo (*P*=0.023); Weeks 4 and 6 are both primary endpoints[3]
- Favorable safety profile and well tolerated[1,4]
  - The most common adverse reactions reported in Voltaren Gel clinical trials were application site reactions in 7% of treated patients[1]
- Less systemic absorption vs a comparable dose of oral diclofenac†[1]
  - On average, 6% of the systemic absorption (basis: 4 g 4 times daily)†
  - On average, 20% of the systemic absorption (basis: 12 g 4 times daily)‡§

*Primary efficacy evaluation at Week 12 for OA of the knee; primary efficacy evaluation at Weeks 4 and 6 for OA of the hand.

†The amount of diclofenac sodium that is systemically absorbed from Voltaren Gel is on average 6% of the systemic exposure from an oral form of diclofenac sodium. Basis: treatment with Voltaren Gel 4 g per joint, 4 times daily applied to 1 knee vs 50 mg, 3 times daily of oral diclofenac.

‡The amount of diclofenac sodium that is systemically absorbed from Voltaren Gel is on average 20% of the systemic exposure from an oral form of diclofenac sodium. Basis: treatment with Voltaren Gel 12 g per joint, 4 times daily applied to 1 knee vs 50 mg, 3 times daily of oral diclofenac.

§Not an approved dose.

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Important Safety Information

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Cardiovascular Risk

- **Non-steroidal anti-inflammatory drugs (NSAIDs) may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk** *[see Warnings and Precautions].*
- **Voltaren Gel is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery** *[see Contraindications].*

Gastrointestinal Risk

- **NSAIDs cause an increased risk of serious gastrointestinal 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 are at greater risk for serious gastrointestinal events** *[see Warnings and Precautions].*

The most common adverse reactions reported in Voltaren Gel clinical trials were application site reactions in 7% of treated patients. With all NSAIDs there may be an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal.

The use of Voltaren Gel is contraindicated in patients with a known hypersensitivity to diclofenac.

Voltaren Gel should not be administered in patients who have experienced asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal, anaphylactic-like reactions to NSAIDs have been reported in such patients.

Voltaren Gel should not be used in combination with other oral NSAIDs or aspirin because of the potential for increased adverse effects. Similarly, combined use of Voltaren Gel with other topical products, such as sunscreens and cosmetics, on the same skin area has not been tested and should be avoided because of the potential to alter local tolerability and absorption.

Safety and effectiveness in pediatric patients have not been established.

Special Precautions

- Showering/bathing should be avoided for at least 1 hour after the application. Patient should wash his/her hands after use, unless the hands are the treated joint. If Voltaren Gel is applied to the hand(s) for treatment, patient should not wash the treated hand(s) for at least 1 hour after the application.
- Voltaren Gel should not be applied to open wounds.
- Contact of Voltaren Gel with eyes and mucous membranes should be avoided.
- External heat and/or occlusive dressings should not be applied to treated joints.
- Exposure of the treated joint(s) to sunlight should be avoided.
- Voltaren Gel should not be used concomitantly with sunscreens, cosmetics, lotions, moisturizers, insect repellants, or other topical medications on the same skin sites has not been evaluated.
- Concomitant use of Voltaren Gel with oral non-steroidal anti-inflammatory drugs (NSAIDs) has not been evaluated, and may increase adverse NSAIDs effects.
- Wearing of clothing or gloves should be avoided for at least 10 minutes after applying Voltaren Gel.

WARNINGS AND PRECAUTIONS

Cardiovascular Thrombotic Events

Clinical trials of several COX-2 selective and nonselective NSAIDs of up to three years duration have shown an increased risk of serious cardiovascular (CV) thrombotic events, myocardial infarction, and stroke, which can be fatal. All NSAIDs, both COX-2 selective and nonselective, may have a similar risk.

Patients with known CV disease or risk factors for CV disease may be at greater risk. To minimize the potential risk for an adverse CV event in patients treated with NSAIDs, the lowest effective dose should be used for the shortest duration possible. Physicians and patients should remain alert for the development of such events, even in the absence of previous CV symptoms. Patients should be informed about the signs and/or symptoms of serious CV toxicity and the steps to take if they occur.

There is no consistent evidence that concurrent use of aspirin mitigates the increased risk of serious CV thrombotic events associated with NSAIDs use. The concurrent use of aspirin and NSAIDs such as diclofenac, does increase the risk of serious GI events *[see Warnings and Precautions].*

Two large, controlled, clinical trials of a COX-2 selective NSAID for the treatment of pain in the first 10-14 days following CABG surgery found an increased incidence of myocardial infarction and stroke *[see Contraindications].*

Gastrointestinal Effects — Risk of GI Ulceration, Bleeding, and Perforation

NSAIDs, including diclofenac, can cause serious gastrointestinal (GI) events including bleeding, ulceration, and perforation of the stomach, small intestine or large intestine, which can be fatal. These serious adverse events can occur at any time, with or without warning symptoms, in patients treated with NSAIDs. Only one in five patients who develop a serious upper GI adverse event on NSAID therapy is symptomatic. Upper GI ulcers, gross bleeding, or perforation caused by NSAIDs occur in approximately 1% of patients treated for 3-6 months, and in about 2-4% of patients treated for one year. These trends continue with longer duration of use, increasing the likelihood of developing a serious GI event at some time during the course of therapy. However, even short-term therapy is not without risk.

NSAIDs should be prescribed with extreme caution in patients with a prior history of ulcer disease or gastrointestinal bleeding. Patients with a prior history of peptic ulcer disease and/or gastrointestinal bleeding who use NSAIDs have a greater than 10-fold increased risk for developing a GI bleed compared to patients with neither of these risk factors. Other factors that increase the risk of GI bleeding in patients treated with NSAIDs include concomitant use of oral corticosteroids or anticoagulants, longer duration of NSAIDs therapy, smoking, use of alcohol, older age, and poor general health status. Most spontaneous reports of fatal GI events are in elderly or debilitated patients and therefore special care should be taken in treating this population.

To minimize the potential risk for an adverse GI event, the lowest effective dose should be used for the shortest possible duration. Physicians and patients should remain alert for signs and symptoms of GI ulceration and bleeding during diclofenac therapy and promptly initiate additional evaluation and treatment if a serious GI adverse event is suspected. For high-risk patients, alternate therapies that do not involve NSAIDs should be considered.

Hepatic Effects

In addition to the borderline elevations of one or more liver tests that may occur in up to 15% of patients taking NSAIDs, in clinical trials of oral diclofenac of up to 3 years in duration, notable elevations of ALT or AST (approximately three or more times the upper limit of normal) have been reported in from 1-5% of patients including elevations of more than 8 times the ULN. In addition to enzyme elevations seen in clinical trials, postmarketing surveillance has reported cases of severe hepatic reactions, including liver necrosis, jaundice, fulminant hepatitis with and without jaundice, and liver failure with rates generally higher than for other NSAIDs. Some of these reported cases resulted in fatalities or liver transplantation. Physicians should measure transaminases periodically in patients receiving long-term therapy with oral diclofenac, because severe hepatotoxicity may develop without a prodrome of distinguishing symptoms. The optimum times for making the first and subsequent transaminase measurements are not known. In one U.S. trial (open-label) that involved 3,700 patients monitored first at 8 weeks and 1,200 patients monitored again at 24 weeks, almost all meaningful elevations in transaminases were detected before patients became symptomatic. In 42 of the 51 patients in all trials who developed marked transaminase elevations, abnormal tests occurred during the first 2 months of therapy with diclofenac. Postmarketing experience has shown severe hepatic reactions can occur at any time during treatment with oral diclofenac. Cases of drug-induced hepatotoxicity have been reported in the first month, and in some cases, the first 2 months of therapy. Based on these experiences, transaminases should be monitored within 4 to 8 weeks after initiating treatment with oral diclofenac.

If abnormal liver tests persist or worsen, if clinical signs and/or symptoms consistent with liver disease develop, or if systemic manifestations occur (e.g., eosinophilia, rash), Voltaren Gel should be discontinued immediately.

To minimize the possibility that hepatic injury will become severe between transaminase measurements, physicians should inform patients of the warning signs and symptoms of hepatotoxicity (e.g., nausea, fatigue, lethargy, pruritus, jaundice, right upper quadrant tenderness, and "flu-like" symptoms), and the appropriate action patients should take if these signs and symptoms appear.

Hypertension

NSAIDs, including Voltaren Gel, can lead to the onset of new hypertension or worsening of preexisting hypertension, either of which may contribute to the increased incidence of cardiovascular events. Patients taking thiazides or loop diuretics may have impaired response to these therapies when taking NSAIDs. NSAIDs, including Voltaren Gel should be used with caution in patients with hypertension. Blood pressure should be monitored closely during the initiation of therapy with Voltaren Gel and throughout the course of therapy.

Congestive Heart Failure and Edema

Fluid retention and edema have been observed in some patients treated with NSAIDs, including Voltaren Gel. Voltaren Gel should be used with caution in patients with fluid retention or heart failure.

Renal Effects

Long-term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury. Renal toxicity has also been seen in patients in whom renal prostaglandins have a compensatory role in the maintenance of renal perfusion. In these patients, administration of an NSAID may cause a dose-dependent reduction in prostaglandin formation and, secondarily, in renal blood flow, which may precipitate overt renal decompensation. Patients at greatest risk of this reaction are those with impaired renal function, heart failure, liver dysfunction, those taking diuretics and ACE inhibitors, and the elderly. Discontinuation of NSAID therapy is usually followed by recovery to the pretreatment state.

No information is available from controlled clinical studies regarding the use of Voltaren Gel in patients with advanced renal disease. Therefore, treatment with Voltaren Gel is not recommended in patients with advanced renal disease. If Voltaren Gel therapy is initiated, close monitoring of the patient's renal function is advisable.

Anaphylactoid Reactions

As with other NSAIDs, anaphylactoid reactions may occur in patients without prior exposure to Voltaren Gel. Voltaren Gel should not be given to patients with the aspirin triad. This symptom complex typically occurs in asthmatic patients who experience rhinitis with or without nasal polyps, or who exhibit severe, potentially fatal bronchospasm after taking aspirin or other NSAIDs *[see Contraindications, Warnings and Precautions].* Emergency help should be sought in cases where an anaphylactoid reaction occurs.

Skin Reactions

NSAIDs, including Voltaren Gel, can cause serious skin adverse events such as exfoliative dermatitis, Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. These serious events may occur without warning. Patients should be informed about the signs and symptoms of serious skin manifestations, and the use of the drug should be discontinued at the first appearance of skin rash or any other signs of hypersensitivity.

Voltaren Gel should not be applied to open skin wounds, infections, inflammations, or exfoliative dermatitis, as it may affect absorption and tolerability of the drug. Voltaren Gel should not be allowed to come into contact with the eyes or with mucous membranes.

The effect of Voltaren Gel under occlusive dressings has not been evaluated, and should be avoided.

NEW
Voltaren® Gel
(diclofenac sodium topical gel) 1%

Easy to Dose...

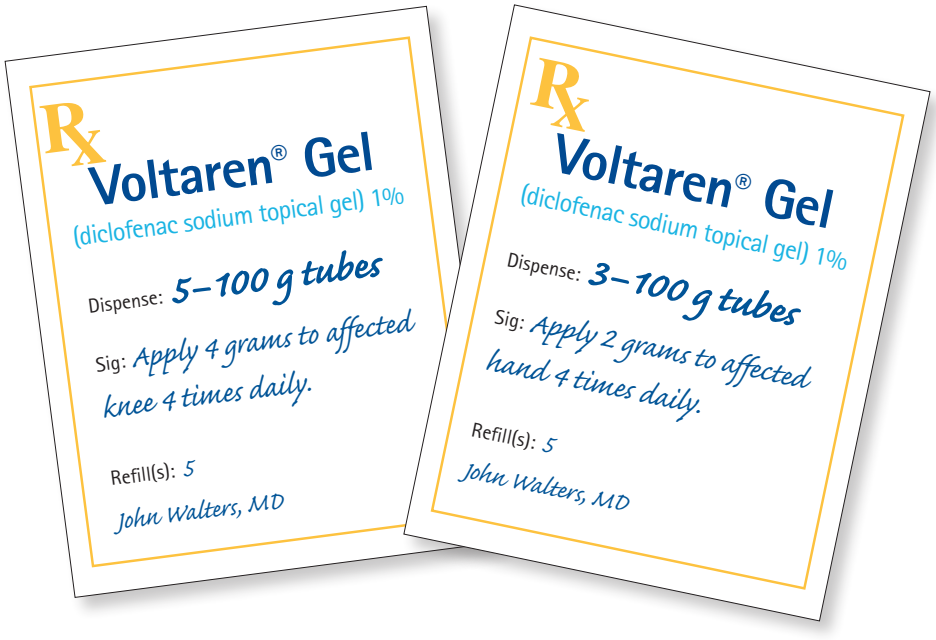
Affected joint	Dosage/ administration	Maximum total grams per day per joint	Total grams per month	Tubes per month
Lower Extremity: (eg, knee, ankle, or foot*)	4 g per joint, 4 times daily	16 g	480 g	5
Upper Extremity: (eg, elbow, wrist, or hand†)	2 g per joint, 4 times daily	8 g	240 g	3

Note: Total dosage should not exceed 32 grams per day over all affected joints.

*The entire foot includes the sole, top of foot, and the toes.

†The entire hand includes the palm, back of the hands, and the fingers.

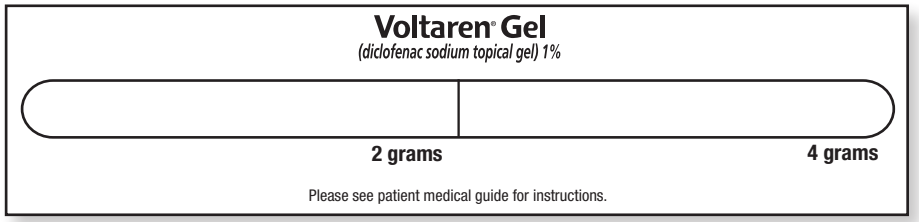
Easy to Prescribe...

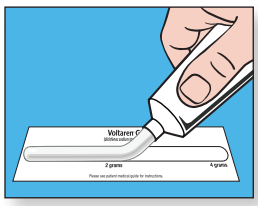


Please see accompanying full Prescribing Information for Warnings and Contraindications.

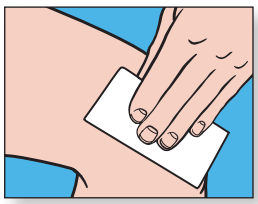
Easy to Use...

- The Voltaren® Gel dosing card, included in drug carton, can be used to apply the gel to help ensure proper dosing
- A new dosing card should be used for each application of drug product

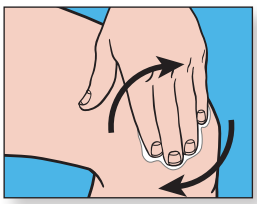




Measure... to the appropriate 2-gram or 4-gram line



Apply... to the affected joint



Rub... over the entire affected joint, ensuring accurate application

Important Safety Information

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Cardiovascular Risk

- **Non-steroidal anti-inflammatory drugs (NSAIDs) may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk *[see Warnings and Precautions].***
- **Voltaren Gel is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery *[see Contraindications].***

Gastrointestinal Risk

- **NSAIDs cause an increased risk of serious gastrointestinal 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 are at greater risk for serious gastrointestinal events *[see Warnings and Precautions].***

The most common adverse reactions reported in Voltaren Gel clinical trials were application site reactions in 7% of treated patients. With all NSAIDs there may be an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal.

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Voltaren Gel should not be used in combination with other oral NSAIDs or aspirin because of the potential for increased adverse effects. Similarly, combined use of Voltaren Gel with other topical products, such as sunscreens and cosmetics, on the same skin area has not been tested and should be avoided because of the potential to alter local tolerability and absorption.

Safety and effectiveness in pediatric patients have not been established.

Please see pages 3 and 6 for additional Important Safety Information.
Please see accompanying full Prescribing Information for Warnings and Contraindications.

Visit www.voltarengel.com for more information

NEW
Voltaren® Gel
(diclofenac sodium topical gel) 1%

Pregnancy
As with other NSAIDs, Voltaren® Gel should be avoided in late pregnancy, because it may cause premature closure of the ductus arteriosus.

Corticosteroid treatment
Voltaren Gel cannot be expected to substitute for corticosteroids or to treat corticosteroid insufficiency. Abrupt discontinuation of corticosteroids may lead to exacerbation of corticosteroid-responsive illness. Patients on prolonged corticosteroid therapy should have their therapy tapered slowly if a decision is made to discontinue corticosteroids.

Inflammation
The pharmacological activity of diclofenac in reducing inflammation, and possibly fever, may diminish the utility of these diagnostic signs in detecting infectious complications of presumed noninfectious, painful conditions.

Hematological Effects
Anemia is sometimes seen in patients receiving NSAIDs. This may be due to fluid retention, occult or gross GI blood loss, or an incompletely described effect upon erythropoeisis. Patients on long-term treatment with NSAIDs, including Voltaren Gel, should have their hemoglobin or hematocrit checked if they exhibit any signs or symptoms of anemia or blood loss.

NSAIDs inhibit platelet aggregation and have been shown to prolong bleeding time in some patients. Unlike aspirin, their effect on platelet function is quantitatively less, of shorter duration, and reversible. Patients treated with Voltaren Gel who may be adversely affected by alteration in platelet function, such as those with coagulation disorders or patients receiving anticoagulants should be carefully monitored.

Preexisting Asthma
Patients with asthma may have aspirin-sensitive asthma. The use of aspirin in patients with aspirin-sensitive asthma has been associated with severe bronchospasm, which can be fatal. Since cross reactivity, including bronchospasm, between aspirin and other non-steroidal anti-inflammatory drugs has been reported in such aspirin-sensitive patients, Voltaren Gel should not be administered to patients with this form of aspirin sensitivity and should be used with caution in patients with preexisting asthma.

Sun Exposure
Patients should minimize or avoid exposure to natural or artificial sunlight on treated areas because studies in animals indicated topical diclofenac treatment resulted in an earlier onset of ultraviolet light-induced skin tumors. The potential effects of Voltaren Gel on skin response to ultraviolet damage in humans are not known.

Eye Exposure
Contact of Voltaren Gel with eyes and mucosa, although not studied, should be avoided. Patients should be advised that if eye contact occurs, they should immediately wash out the eye with water or saline and consult a physician if irritation persists for more than an hour.

Laboratory Tests
Because serious GI tract ulcerations and bleeding can occur without warning symptoms, physicians should monitor for signs or symptoms of GI bleeding. Patients on long-term treatment with NSAIDs, should have a CBC and a chemistry profile checked periodically. If abnormal liver tests or renal tests persist or worsen, Voltaren Gel should be discontinued.

ADVERSE REACTIONS

Clinical Studies 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 with rates in the clinical trials of another drug and may not reflect the rates observed in practice.

During clinical development, 913 patients were exposed to Voltaren Gel in randomized, double-blind, multicenter, vehicle-controlled, parallel-group studies in osteoarthritis of the superficial joints of the extremities. Of these, 513 patients received Voltaren Gel for osteoarthritis of the knee and 400 were treated for osteoarthritis of the hand. Additionally, 583 patients were exposed to Voltaren Gel in an uncontrolled, open-label, long-term safety trial in osteoarthritis of the knee. Of these, 355 patients were treated for osteoarthritis of 1 knee and 228 were treated for osteoarthritis of both knees. Duration of exposure ranged from 8 to 12 weeks for the placebo-controlled studies, and up to 12 months for the open-label safety trial.

Short-Term Placebo-Controlled Trials:
Adverse reactions observed in at least 1% of patients treated with Voltaren Gel: Non-serious adverse reactions that were reported during the short-term placebo-controlled studies comparing Voltaren Gel and placebo (vehicle gel) over study periods of 8 to 12 weeks (16 g per day), were application site reactions. These were the only adverse reactions that occurred in >1% of treated patients with a greater frequency in the Voltaren Gel group (7%) than the placebo group (2%).

Table 1 lists the types of application site reactions reported. Application site dermatitis was the most frequent type of application site reaction and was reported by 4% of patients treated with Voltaren Gel, compared to 1% of placebo patients.

Table 1. Non-serious Application Site Adverse Reactions (≥1% Voltaren Gel Patients) — Short-term Controlled Trials

Adverse Reactions*	Voltaren Gel N = 913	Placebo (vehicle) N = 876
	N (%)	N (%)
Any application site reaction	*62 (7)*	*19 (2)*
Application site dermatitis	32 (4)	6 (<1)
Application site pruritus	7 (<1)	1 (<1)
Application site erythema	6 (<1)	3 (<1)
Application site paresthesia	5 (<1)	3 (<1)
Application site dryness	4 (<1)	3 (<1)
Application site vesicles	3 (<1)	0
Application site irritation	2 (<1)	0
Application site papules	1 (<1)	0

*Preferred Term according to MedDRA 9.1.

In the placebo-controlled trials, the discontinuation rate due to adverse reactions was 5% for patients treated with Voltaren Gel, and 3% for patients in the placebo group. Application site reactions, including application site dermatitis, were the most frequent reason for treatment discontinuation.

Long-Term Open-Label Safety Trial:
In the open-label, long-term safety study, distribution of adverse reactions was similar to that in the placebo-controlled studies. In this study, where patients were treated for up to 1 year with Voltaren Gel up to 32 g per day, application site dermatitis was observed in 11% of patients. Adverse reactions that led to the discontinuation of the study drug were experienced in 12% of patients. The most common adverse reaction that led to discontinuation of the study was application site dermatitis, which was experienced by 6% of patients.

DRUG INTERACTIONS

Aspirin
When diclofenac is administered with aspirin, the binding of diclofenac to protein is reduced, although the clearance of free diclofenac is not altered. The clinical significance of this interaction is not known; however, as with other NSAIDs, concomitant administration of diclofenac and aspirin is not generally recommended because of the potential of increased adverse effects.

Anticoagulants
The effects of anticoagulants such as warfarin and NSAIDs on GI bleeding are synergistic, such that users of both drugs together have a risk of serious GI bleeding higher than users of either drug alone.

ACE-Inhibitors
NSAIDs may diminish the antihypertensive effect of angiotensin converting enzyme (ACE) inhibitors. This interaction should be given consideration in patients taking NSAIDs concomitantly with ACE-inhibitors.

Diuretics
Clinical studies, as well as post-marketing observations, have shown that NSAIDs can reduce the natriuretic effect of furosemide and thiazides in some patients. The response has been attributed to inhibition of renal prostaglandin synthesis. During concomitant therapy with NSAIDs, the patient should be observed closely for signs of renal failure *[see Warnings and Precautions]*, as well as to assure diuretic efficacy.

Lithium
NSAIDs have produced an elevation of plasma lithium levels and a reduction in renal lithium clearance. The mean minimum lithium concentration increased 15% and the renal clearance was decreased by approximately 20%. These effects have been attributed to inhibition of renal prostaglandin synthesis by the NSAID. Thus, when NSAIDs, including diclofenac, and lithium are administered concurrently, patients should be observed carefully for signs of lithium toxicity.

Methotrexate
NSAIDs have been reported to competitively inhibit methotrexate accumulation in rabbit kidney slices. This may indicate that they could enhance the toxicity of methotrexate. Caution should be used when NSAIDs, including diclofenac, are administered concomitantly with methotrexate.

Cyclosporine
Diclofenac, like other NSAIDs, may affect renal prostaglandins and increase the toxicity of certain drugs. Therefore concomitant therapy with diclofenac may increase cyclosporine's nephrotoxicity. Caution should be used when diclofenac is administered concomitantly with cyclosporine.

Oral Non-steroidal Anti-inflammatory Drugs
Specific interaction studies of Voltaren Gel and oral NSAIDs were not performed. Also, the clinical trials of Voltaren Gel prohibited concomitant use of oral NSAIDS. There is systemic exposure to diclofenac following normal use of Voltaren Gel, up to 6% of the systemic levels of a single oral dose of diclofenac sodium *[see Clinical Pharmacology]*. Therefore, concomitant administration of Voltaren Gel with oral NSAIDs or aspirin may result in increased adverse NSAID effects.

Topical Treatments
Concomitant use of Voltaren Gel with other topical products, including topical medications, sunscreens, lotions, moisturizers, and cosmetics, on the same skin site has not been tested and should be avoided because of the potential to alter local tolerability and absorption.

Please see accompanying full Prescribing Information for Warnings and Contraindications.

References: 1. Voltaren Gel [package insert]. Parsippany, NJ: Novartis Consumer Health, Inc; 2007. **2.** Data on file, VOSG-PN-310. **3.** Data on file, VOSG-PE-315. **4.** Data on file, VOSG-PN-309.

Comments or Questions?
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