Diclofenac Sodium Gel

3%

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

Rx only

NET WT. 100 g

Diclofenac Sodium Gel, 3% contains Diclofenac Sodium (30 mg/g).

INACTIVE INGREDIENTS: Benzy alcohol, hydroxyethyl cellulose, methoxypolyethylene glycol 350, PEG-60 hydrogenated castor oil, and purified water.

INDICATIONS: For the topical treatment of actinic keratosis.

WARNING: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

USUAL ADULT DOSAGE: 0.5 g of gel (size of a pea) applied to the affected skin and smoothed into the skin gently, or as directed by your physician. The usual duration of therapy is from 60 to 90 days. Please see package insert for full prescribing information.

Store at 20° - 25°C (68° - 77°F); excursions permitted to 15° - 30°C (59° - 86°F) [see USP Controlled Room Temperature]. Protect from heat. Avoid freezing. See crimp of tube and/or carton for lot number and expiration date.

Manufactured by: TOLMAR Inc., Fort Collins, CO 80526
Distributed by: Global Pharmaceuticals, Division of IMPAX Laboratories, Inc., Philadelphia, PA 19124 02250 Rev. 1 06/13

TOLMAR inc.
701 Centre Avenue
Fort Collins, CO 80526
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Protect from heat. Avoid freezing.

Caution: For external use only. Not for ophthalmic use. Sun avoidance is indicated during therapy.
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Manufactured by: TOLMAR Inc., Fort Collins, CO 80526
Distributed by: Global Pharmaceuticals, Division of IMPAX Laboratories, Inc., Philadelphia, PA 19124 02249 Rev. 1 06/13
Didofenac Sodium Gel

For external use only. Not for opthalmic use.

Rx only
NET WT. 50 g

Manufactured by:
TOLMAR Inc., Fort Collins, CO 80526
Distributed by:
Global Pharmaceuticals, Division of IMPAX Laboratories, Inc.
Philadelphia, PA 19124

LOT and EXP on bottom flap
03440 Rev. 0 06/13

Didofenac Sodium Gel, 3% contains Didofenac Sodium (30 mg/g).

INACTIVE INGREDIENTS: Benzyl alcohol, hydroxyethyl cellulose, methoxy-polyethylene glycol 350, PEG-60 hydrogenated castor oil, and purified water.

INDICATIONS: For the topical treatment of actinic keratosis.

WARNING: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Store at 20° - 25°C (68° - 77°F); excursions permitted to 15° - 30°C (59° - 86°F) [see USP Controlled Room Temperature]. Protect from heat. Avoid freezing. USUAL ADULT DOSAGE: 0.5 g of gel (size of a pea) applied to the affected skin and smoothed into the skin gently, or as directed by your physician. The usual duration of therapy is from 60 to 90 days.

Caution: For external use only. Not for opthalmic use. Sun avoidance is indicated during therapy. Please see package insert for full prescribing information.
Diclofenac Sodium Gel, 3%

**FOR EXTERNAL USE ONLY
NOT FOR ORAL USE**

**CONTRAINDICATIONS**

Lidocaine, prilocaine, or any components of this product, including hydroxypropyl methylcellulose, acepromazine, phenylalanine, triclofos or antihistamines.

**WARNINGS**

Skin irritation, skin ulcers, bullae, blisters, or any other skin disorder that needs treatment.

**PRECAUTIONS**

Skin irritation, skin ulcers, bullae, blisters, or any other skin disorder that needs treatment.

**DIAGNOSIS**

Skin irritation, skin ulcers, bullae, blisters, or any other skin disorder that needs treatment.

**DOSE AND ADMINISTRATION**

Skin irritation, skin ulcers, bullae, blisters, or any other skin disorder that needs treatment.

**SIDE EFFECTS**

Skin irritation, skin ulcers, bullae, blisters, or any other skin disorder that needs treatment.

**OVERDOSAGE**

Skin irritation, skin ulcers, bullae, blisters, or any other skin disorder that needs treatment.

**ADVERSE REACTIONS**

Skin irritation, skin ulcers, bullae, blisters, or any other skin disorder that needs treatment.

**CLASSESS N%**

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**ADVERSE REACTIONS**

Skin irritation, skin ulcers, bullae, blisters, or any other skin disorder that needs treatment.
ADVERSE REACTIONS

Of the 211 patients treated with diclofenac sodium gel, 3%, 172 (82%) experienced AEs involving skin and the application site compared to 160 (75%) treated with vehicle. The AEs reported at an incidence of >1% for patients treated with either diclofenac sodium gel, 3% or vehicle (60- and 90-day treatment periods) during the phase 3 studies. These discontinuations were mainly due to skin irritation or related cutaneous adverse reactions. Of the 211 subjects treated with diclofenac sodium gel, 3% in controlled clinical studies, 143 subjects were 65 and over. Of those 143 subjects, 55 subjects were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Diclofenac sodium gel is available in tubes of 100 g and 50 g. Each gram of gel contains 30 mg of diclofenac sodium.

Skin and Appendages

The absorption of diclofenac is dependent upon the size of the lesion site. Assure that enough Diclofenac Sodium Gel, 3% is applied to adequately cover each lesion. Normally 0.5 g of gel is used on each 5 cm x 5 cm lesion site. The recommended duration of therapy is from 60 days to 90 days. Complete healing of the lesion(s) or optimal therapeutic effect may be seen within 30 days of therapy. Lesions that do not respond to therapy should be carefully re-evaluated and management reconsidered.

Supportive and symptomatic treatment should be given for complications such as renal failure, convulsions, gastrointestinal bleeding, impotence, vaginal bleeding. Diclofenac sodium gel is not suited for use in the diagnosis or treatment of lesions which have been recently exposed to the sun or are in active inflammatory phases of healing.

Distributed by: Global Pharmaceuticals, Division of IMPAX Laboratories, Inc.
Fort Collins, CO 80526

3.4 OVERDOSAGE

In cases of overdose, Diclofenac Sodium Gel, 3% is unlikely to produce symptoms severe enough to require management. The gel contains 30 mg of diclofenac sodium per gram. The following are observed in animal studies and with the use of diclofenac tablets (whether considered related to treatment or not). The gel is not considered to be toxic and is not absorbed extensively during the studies. The majority of these reactions were noted to subside in severity by 24 hours after discontinuance of the gel application or the discontinuation of therapy. In a multi-center trial in which Diclofenac Sodium Gel, 3% was applied to a single area along with a 4 cm QFT bandage once daily for 7 days, the majority of the reactions noted were noted to subside in severity by 24 hours after discontinuance of the gel application or the discontinuation of therapy. In a multi-center trial in which Diclofenac Sodium Gel, 3% was applied to a single area along with a 4 cm QFT bandage once daily for 7 days, the majority of the reactions noted were noted to subside in severity by 24 hours after discontinuance of the gel application or the discontinuation of therapy.

If the patient is treated with diclofenac sodium gel, 3%, the following tablets should not be used: a) phenylbutazone, b) indomethacin, c) aspirin, d) ibuprofen, e) naproxen, f) ketoprofen, g) flurbiprofen, h) nabumetone, i) celecoxib, j) valdecoxib, k) meloxicam. If the patient is treated with diclofenac sodium gel, 3%, the following medications should not be used: a) isoniazid, b) disulfram, c) pentobarbital, d) tricyclic antidepressants, e) MAO inhibitors, f) phenothiazines, g) lithium, h) anticoagulants, i) beta blockers, j) digitalis glycosides, k) ketoconazole, l) cimetidine, m) ranitidine, n) metoclopramide, o) antifungal agents, p) 5-HT3 antagonists, q) selective serotonin reuptake inhibitors, r) selective serotonin-norepinephrine reuptake inhibitors, s) antiplatelet agents, t) warfarin, u) trazodone, v) non-SA[H]NSAIDs, w) salicylates, x) azathioprine, y) cyclophosphamide, z) gold salts.

In animal studies, Diclofenac Sodium Gel, 3% exhibited a low genetic toxicity risk due to negative results in bacterial reverse mutation test (Ames assay), mouse lymphoma assay, and an in vitro chromosomal aberration test in human lymphocytes. In three in vivo mammalian cell Transformation assays, Diclofenac Sodium Gel, 3% exhibited negative results. In an in vivo rat bone marrow micronucleus assay, Diclofenac Sodium Gel, 3% was negative. In a 2-year carcinogenicity study conducted in CD-1 mice, a single dose of diclofenac sodium (100 mg/kg/day) administered orally did not cause tumors. A single dose of diclofenac sodium (100 mg/kg/day) administered orally did not cause tumors. Diclofenac sodium gel, 3% did not induce tumors in rats when administered orally at dose levels up to 100 mg/kg/day. In a 2-year carcinogenicity study conducted in CD-1 mice, a single dose of diclofenac sodium (100 mg/kg/day) administered orally did not cause tumors.

Diclofenac sodium gel, 3% is a topical gel. After application, the gel should be washed off the skin with soap and water. 

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