DICLONA- lidocaine 4.5%, diclofenac 1% gel
Clinic Pharma

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.

Diclona™

Diclona

(Lidocaine 4.5%, Diclofenac Sodium 1%)

Rx only - Gel

DESCRIPTION

Diclona™ is comprised of a gel inside of a 3.5oz tube containing 4.5% Lidocaine and 1% Diclofenac Sodium.

Inactive ingredients: Aloe Barbadensis (Aloe Vera) Leaf Juice, Arnica Montana Flower Extract, Boswellia Serrata Extract, Carbomer, Dimethyl Sulfoxide, Ethylhexylglycerin, Eucalyptus Globulus Leaf Oil, Methylsulfonylmethane, Phenoxyethanol, Prunus Amygdalus Dulcis (Sweet Almond) Oil, SD Alcohol 40-B, Sorbitol, Water.

CLINICAL PHARMACOLOGY

Pharmacodynamics

Lidocaine is an amide-type local anesthetic agent. The penetration of lidocaine into intact skin after application of Diclona Gel is sufficient to produce analgesic effect, but less than the amount necessary to produce a complete sensory block. The mechanism of action of diclofenac sodium in the treatment of actinic keratoses (AK) is unknown. The contribution to efficacy of individual components of the vehicle has not been established.

Pharmacokinetics

Absorption

The amount of lidocaine systemically absorbed from Diclona Gel is directly related to both the duration of application and the surface area over which it is applied. When Diclona Gel is applied topically, diclofenac sodium is absorbed into the epidermis. The systematic bioavailability after topical application of diclofenac sodium is lower than after oral dosing.

Distribution

At concentrations produced by application of Diclona Gel, approximately 70% of the lidocaine dose is reported to be bound to plasma proteins, primarily alpha-1-acid glycoprotein. At higher plasma concentrations (1 to 4 mcg/mL of free base), the plasma protein binding of lidocaine is concentration dependent. Diclofenac sodium binds tightly to serum albumin.

Metabolism

It is not known if Diclona Gel is metabolized in the skin. Metabolism of diclofenac sodium following topical administration is thought to be similar to that after oral administration. The small amounts of diclofenac sodium and its metabolites appearing in the plasma following topical administration makes the quantification of specific metabolites imprecise.

Excretion

Lidocaine and its metabolites are excreted by the kidneys. Less than 10% of lidocaine is excreted unchanged. The half-life of lidocaine elimination from the plasma following IV administration is 81 to 149 minutes (mean 107 ± 22 SD, n = 15). The systemic clearance is 0.33 to 0.90 L/min (mean 0.64 ± 2 max max 0.18 SD, n = 15). Diclofenac sodium and its metabolites are excreted mainly in the urine after oral dosing.

INDICATION AND USAGE

Diclona™ is indicated for relief of pain associated with arthritis, backache, cramps, discomfort, neckache, soreness, sprains, strains. It should be applied only to intact skin. Sun avoidance is indicated during therapy.

CONTRAINDICATIONS

Diclona™ is contraindicated in patients with a known history of sensitivity to local anesthetics of the amide type, or to any other component of the product. Diclona Gel is contraindicated in patients with a known hypersensitivity to diclofenac sodium. Diclona Gel is contraindicated in patients in the setting of coronary artery bypass graft (CABG) surgery.

WARNINGS

Medicines intended to be applied to the skin should not be swallowed.

Diclona™ is flammable. Keep away from open flame.

You should never heat, microwave, or add the medicine to hot water.

Risk of Methemoglobinemia

Cases of methemoglobinemia have been reported in association with lidocaine use. Although all patients are at risk for methemoglobinemia, patients with glucose-6-phosphate dehydrogenase deficiency, congenital or idiopathic methemoglobinemia, cardiac or pulmonary compromise, infants under 6 months of age, and concurrent exposure to oxidizing agents or their metabolites are more susceptible to developing the condition. If lidocaine must be used in these patients, close monitoring for symptoms and signs of methemoglobinemia is recommended. Signs of methemoglobinemia may occur immediately or may be delayed some hours after exposure and are characterized by a cyanotic skin discoloration and/or abnormal coloration of the blood.

Methemoglobin levels may continue to rise; therefore, immediate treatment is required to avert more serious central nervous system and cardiovascular adverse effects, including seizures, coma, arrhythmias, and death.

Risk of Serious Cardiovascular 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.

Fetal Toxicity

Avoid use of NSAIDs in pregnant women at about 30 weeks gestation and later. NSAIDs increase the risk of premature closure of the fetal ductus arteriosus at approximately this gestational age. Use of NSAIDs at about 20 weeks gestation or later in pregnancy may cause fetal renal dysfunction leading to oligohydramnios and, in some case, neonatal renal impairment. If NSAID treatment is necessary between about 20 weeks and 30 weeks gestation, limit Diclona Gel use to the lowest effective dose and shortest duration possible.

Serious Skin Reactions

Drug Rash with Eosinophilia and Systemic Symptoms (DRESS)

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) has been reported in patients taking NSAIDs such as Diclona Gel. DRESS typically, although not exclusively, presents with fever, rash, lymphadenopathy, and/or facial swelling.

Heart Failure and Edema

The Coxib and traditional NSAID Trialists' Collaboration meta-analysis of randomized controlled trials demonstrated an approximately two-fold increase in hospitalizations for heart failure in COX-2 selective-treated patients and nonselective NSAID-treated patients compared to placebo-treated patients. Avoid the use of Diclona Gel in patients with severe heart failure unless benefits are expected to outweigh the risk of worsening heart failure. If Diclona Gel is used in patients with severe heart failure, monitor patients for signs of worsening heart failure.

PRECAUTIONS

General

Diclona™ should be used with caution in patients with active gastrointestinal ulceration or bleeding and severe renal or hepatic impairments. Diclona Gel should not be applied to open skin wounds, infections, or exfoliative dermatitis.

Hepatic Disease

Patients with severe hepatic disease are at greater risk of developing toxic blood concentrations of lidocaine, because of their inability to metabolize lidocaine normally.

Allergic Reactions

Patients allergic to para-aminobenzoic acid derivatives (procaine, tetracaine, benzocaine, etc.) have not shown cross sensitivity to lidocaine. However, Diclona Gel should be used with caution in patients with a history of drug sensitivities, especially if the etiologic agent is uncertain.

Non-intact Skin

Application to broken or inflamed skin, although not tested, may result in higher blood concentrations of lidocaine from increased absorption. Diclona Gel is only recommended for use on intact skin.

External Heat Sources

Placement of external heat sources, such as heating pads or electric blankets, over Diclona Gel is not recommended as this has not been evaluated and may increase plasma lidocaine levels.

Eye Exposure

The contact of Diclona Gel with eyes, although not studied, should be avoided based on the findings of severe eye irritation with the use of similar products in animals. If eye contact occurs, immediately wash out the eye with water or saline and protect the eye until sensation returns.

Information for Patients Methemoglobinemia

Inform patients that use of local anesthetics may cause methemoglobinemia, a serious condition that must be treated promptly. Advise patients or caregivers to stop use and seek immediate medical attention if they or someone in their care experience the following signs or symptoms: pale, gray, or blue colored skin (cyanosis); headache; rapid heart rate; shortness of breath; lightheadedness; or fatigue.

Drug Interactions

Specific interaction studies between Diclona Gel and other topical or oral agents were not performed.

Oral Nonsteroidal Anti-Inflammatory Drugs

Although low, there is systemic exposure to diclofenac sodium following labeled use of Diclona Gel. Therefore, concomitant administration of Diclona Gel with oral NSAIDs or aspirin may result in increased NSAID adverse effects.

Antiarrhythmic Drugs

Diclona Gel should be used with caution in patients receiving Class I antiarrhythmic drugs (such as tocainide and mexiletine) since the toxic effects are additive and potentially synergistic.

Local Anesthetics

When Diclona Gel is used concomitantly with other products containing local anesthetic agents, the amount absorbed from all formulations must be considered.

Drugs That May Cause Methemoglobinemia When Used with Diclona Gel

Patients who are administered local anesthetics are at increased risk of developing methemoglobinemia when concurrently exposed to the following drugs, which could include other local anesthetics:

Examples of Drugs Associated with Methemoglobinemia:

Class Examples

Nitrates/Nitrites nitric oxide, nitroglycerin, nitroprusside, nitrous oxide Local anesthetics

articaine, benzocaine, bupivacaine, lidocaine, mepivacaine, prilocaine, procaine, ropivacaine, tetracaine

Antineoplastic agents cyclophosphamide, flutamide, hydroxyurea, ifosfamide, rasburicase, antibiotics dapsone, nitrofurantoin, para-aminosalicylic acid, sulfonamides, antimalarials chloroquine, primaquine anticonvulsants, phenobarbital, phenytoin, sodium valproate, opher drugs acetaminophen, metoclopramide, quinine, sulfasalazine carcinogenesis, mutagenesis.

Impairment of Fertility

The effect of Diclona Gel on fertility has not been studied.

Pregnancy

Teratogenic Effects

Pregnancy Category B.

Diclona Gel has not been studied in pregnancy.

Labor and Delivery

Diclona Gel has not been studied in labor and delivery.

Nursing Mothers

Diclona Gel has not been studied in nursing mothers.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

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.

ADVERSE REACTIONS

Application Site Reactions

During or immediately after treatment with Diclona™, the skin at the site of application may develop blisters, bruising, burning sensation, depigmentation, dermatitis, discoloration, edema, erythema, exfoliation, irritation, papules, petechia, pruritus, vesicles, or may be the locus of abnormal sensation. These reactions are generally mild and transient, resolving spontaneously within a few minutes to hours.

Other Adverse Events

Due to the nature and limitation of spontaneous reports in post marketing surveillance, causality has not been established for additional reported adverse events including:

Asthenia, confusion, disorientation, dizziness, headache, hyperesthesia, hypoesthesia, lightheadedness, metallic taste, nausea, nervousness, pain exacerbated, paresthesia, somnolence, taste alteration, vomiting, visual disturbances such as blurred vision, flushing, tinnitus, and tremor.

Systemic (Dose-Related) Reactions

Systemic adverse reactions following appropriate use of Diclona™ are unlikely, due to the small dose absorbed (see CLINICAL PHARMACOLOGY, Pharmacokinetics). Systemic adverse effects of lidocaine is similar in nature to those observed with other amide local anesthetic agents, including CNS excitation and/or depression (light headedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, tinnitus, blurred or double vision, vomiting, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest). Excitatory CNS reactions may be brief or not occur at all, in which case the first manifestation may be drowsiness merging into unconsciousness. Cardiovascular manifestations may include bradycardia, hypotension and cardiovascular collapse leading to arrest.

OVERDOSAGE

Lidocaine overdose from cutaneous absorption is rare but could occur. Excessive dosing by applying Diclona Gel to larger areas could result in increased absorption of lidocaine and high blood concentrations, leading to serious adverse effects (see ADVERSE REACTIONS, Systemic Reactions). Longer duration of application of more than the recommended number of doses, smaller patients, or impaired elimination may all contribute to increased blood concentration of lidocaine. Due to the low systemic absorption of topically-applied diclofenac sodium, overdosage of diclofenac sodium is unlikely.

DOSAGE AND ADMINISTRATION

Apply Diclona™ to intact skin to cover the most painful area. Clean and dry the affected area. Apply product directly to your skin, up to 4 times daily. Clothing may be worn over the area of application.

If irritation or a burning sensation occurs during application, wash the product off your skin and do not reapply until the irritation subsides.

When Diclona™ is used concomitantly with other products containing local anesthetic agents, the amount absorbed from all formulations must be considered.

HANDLING AND DISPOSAL

Hands should be washed after the handling of Diclona Gel, and eye contact with Diclona Gel should be avoided. Store in a cool, dry place with lid tightly closed.

Diclona™ should be kept out of the reach of children.

HOW SUPPLIED

Diclona™ is available as the following:

1 tube, 3.5oz

NDC 83881-102-35

Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). [See USP Controlled

Room Temperature].

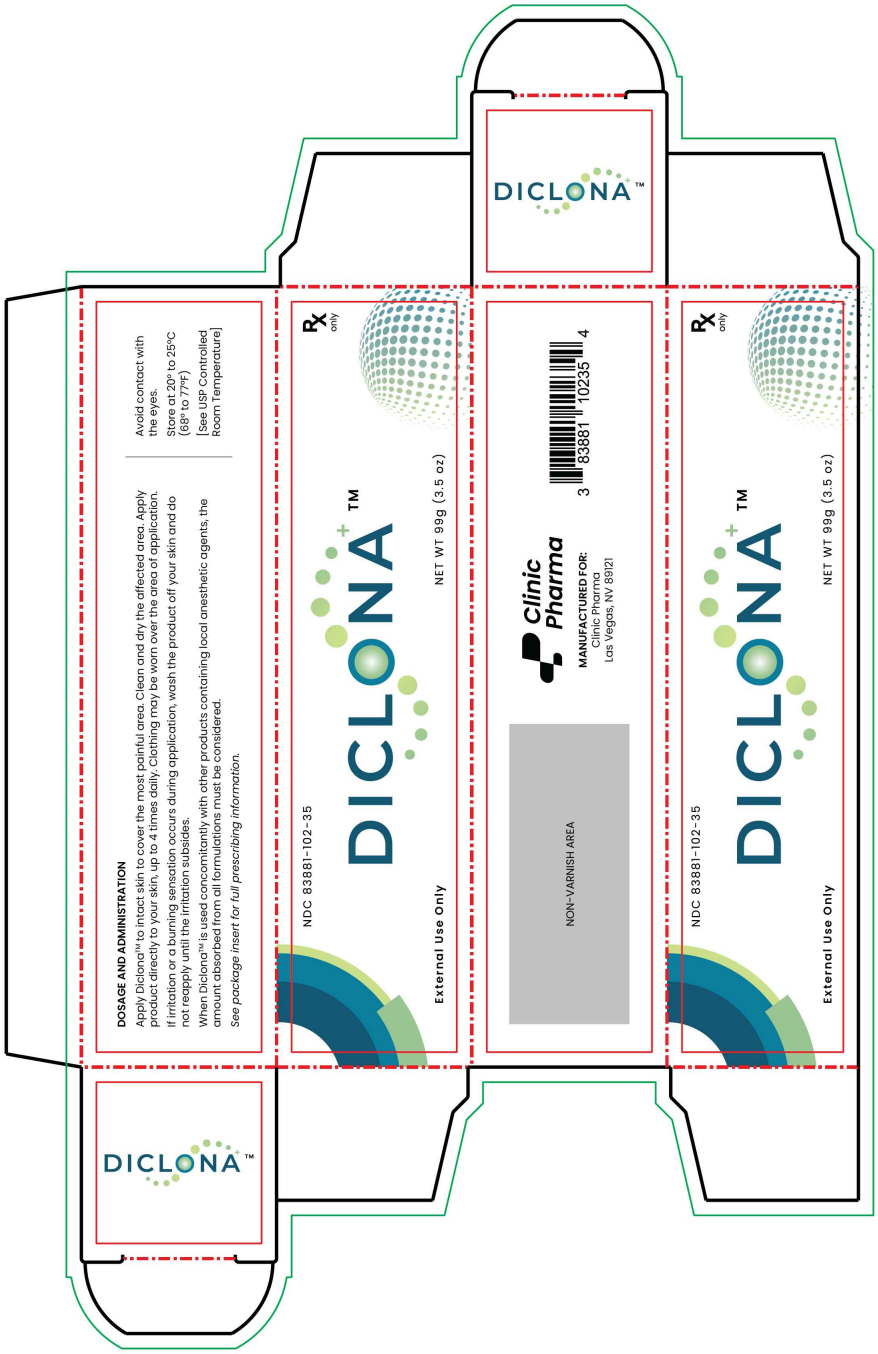
For more information, contact Clinic Pharma, info@clinicpharma.com

Manufactured for:

Clinic Pharma | Las Vegas, NV 89121

MADE IN U.S.A

Package Display



Patient Package Insert

DOSAGE AND ADMINISTRATION
Clean and dry the affected area. Apply Diclona™ directly to intact skin over the most painful area, up to 4 times daily. Clothing may be worn over the area of application.

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HOW SUPPLIED
Diclona™ is available as the following:
1 tube, 3.5 oz
NDC 83881-102-35

Avoid contact with the eyes.
Store at 20° to 25°C (68° to 77°F).
[See USP Controlled Room Temperature]

For more information, contact Clinic Pharma.
info@clinicpharma.com

Clinic Pharma

Manufactured for:
Clinic Pharma
Las Vegas, NV 89121
Printed in the U.S.A.

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Examples of Drugs Associated with Methemoglobinemia:

Class:	*Examples:*
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Local anesthetics:	articaine, benzocaine, bupivacaine, lidocaine, mepivacaine, prilocaine, procaine, ropivacaine, tetracaine
Antineoplastic agents:	cyclophosphamide, flutamide, hydroxyurea, ifosfamide, rasburicase
Antibiotics:	dapsone, nitrofurantoin, para-aminosalicylic acid, sulfonamides
Antimalarials:	chloroquine, primaquine
Anticonvulsants:	phenobarbital, phenytoin, sodium valproate
Other drugs:	acetaminophen, metoclopramide, quinine, sulfasalazine carcinogenesis, mutagenesis.

ADVERSE REACTIONS
Application Site Reactions
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DICLONA

lidocaine 4.5%, diclofenac 1% gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:83881-102
Route of Administration	CUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DICLOFENAC SODIUM (UNII: QTG126297Q) (DICLOFENAC - UNII:144O8QL0L1)	DICLOFENAC SODIUM	0.01 g in 1 g
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	0.045 g in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SORBITOL (UNII: 506T60A25R)	
ALCOHOL (UNII: 3K9958V90M)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
AMINOMETHYLPROPANOL (PERFLUORO-C6-C12 ETHYL)PHOSPHATE (UNII: QCD5R22RNT)	
PRUNUS AMYGDALUS DULCIS (SWEET ALMOND) SEED MEAL (UNII: 3Z252A2K9G)	
BOSWELLIA SERRATA GUM (UNII: 4PW41QCO2M)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:83881-102-35	99 g in 1 TUBE; Type 0: Not a Combination Product	04/15/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/15/2025	

Labeler - Clinic Pharma (119158469)