

COLCIGEL- colchicinum 4x gel
Gensco Laboratories, LLC

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

HIGHLIGHTS OF PRESCRIBING INFORMATION
COLCIGEL

These highlights do not include all the information needed to use colchicine safely and effectively. See full prescribing information for ColciGel®.

Initial U.S. Approval

----- **INDICATIONS AND USAGE** -----

ColciGel® (colchicinum 4X) transdermal gel is an alkaloid indicated for:
Treatment and Prophylaxis of Gout Flares in adults. (1.1)

ColciGel® (colchicinum 4X) is not an analgesic medication and should not be used to treat pain from other causes.

----- **DOSAGE FORMS AND STRENGTHS** -----

ColciGel® is Colchicinum 4X in a transdermal gel base. The gel is viscous and opaque in appearance. ColciGel® is available in 15 mL sealed dispensing containers that produce 0.25 mL of gel per each manual depression of the plunger top (pump). (3)

----- **CONTRAINDICATIONS** -----

Traumatized skin, secondary bacterial infection of the area of proposed application and known hypersensitivity to any of the components. (4)

Revised: 12/2018

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* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Gout Flares

ColciGel® transdermal gel is indicated for prophylaxis and the treatment of acute gout flares.

Treatment of Gout Flares:

ColciGel® gel is indicated for treatment of acute gout flares when used at the first sign of a flare.

Prophylaxis of Gout Flares:

ColciGel® is indicated for prophylaxis of gout flares.

2 DOSAGE AND ADMINISTRATION

Apply 1 - 4 pumps up to four times per day. 1 application = 1 pump (0.25ml) covers an area 4" in diameter.

Children under 16 years of age do not use unless directed by a physician.

DISCARD 6 MONTHS AFTER FIRST USE

3 DOSAGE FORMS AND STRENGTHS

ColciGel® is Colchicinium 4X in a transdermal gel base. The gel is viscous and opaque in appearance. ColciGel® is available in 15 mL sealed dispensing containers that produce 0.25 mL of gel per each manual depression of the plunger top (pump).

4 CONTRAINDICATIONS

Patients with severe renal or severe hepatic impairment should not be given ColciGel® in conjunction with P-gp or strong CYP3A4 inhibitors (this includes all protease inhibitors, except fosamprenavir). In these patients, life-threatening and fatal colchicine toxicity has been reported with **ORAL** colchicine taken in therapeutic doses.

5 WARNINGS

For External Use Only • Avoid Contact With Eyes and Mouth • Keep Out of Reach of

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

PRECAUTIONS

Use in Pregnancy: No human or animal studies on the effect of ColciGel® (colchicium 4X) in pregnancy have been conducted.

Nursing Mothers: It is not known whether ColciGel® (colchicium 4X) is excreted in breast milk.

6 ADVERSE REACTIONS

Prophylaxis and Treatment of Gout Flares: The most commonly reported adverse reaction in clinical trials for the prophylaxis and treatment of gout was mild skin irritation at the site of application.

7 DRUG INTERACTIONS

ColciGel® (Colchicium 4X) is a substrate of the efflux transporter P-glycoprotein (P-gp). Of the cytochrome P450 enzymes tested, CYP3A4 was mainly involved in the metabolism of colchicium. If **ORAL** colchicine is administered with drugs that inhibit P-gp, most of which also inhibit CYP3A4, increased concentrations of colchicium are likely. Fatal drug interactions have been reported. Topical application of ColciGel® has demonstrated insignificant systemic absorption in animal testing and confirmed in limited human pharmacokinetic evaluations and, therefore, poses a limited risk of clinically significant drug interactions. Physicians should, however, ensure that patients are suitable candidates for treatment with ColciGel® and remain alert for signs and symptoms of toxicities related to increased colchicium exposure as a result of a drug interaction. Signs and symptoms of ColciGel® toxicity should be evaluated promptly and, if toxicity is suspected, ColciGel® should be discontinued immediately.

12 CLINICAL PHARMACOLOGY

The mechanism by which colchicium exerts its beneficial effect in patients has not been fully elucidated; however, evidence suggests that colchicium may interfere with the intracellular assembly of the inflammasome complex present in neutrophils and monocytes that mediates activation of interleukin-1 α . Additionally, colchicine disrupts cytoskeletal functions through inhibition of alpha-tubulin polymerization into microtubules and consequently prevents the activation, degranulation, and migration of neutrophils thought to mediate some gout symptoms.

13 NONCLINICAL TOXICOLOGY

Carcinogenesis

Carcinogenicity studies of colchicine have not been conducted. Due to the potential for colchicine to produce aneuploid cells (cells with an unequal number of chromosomes), there is theoretically an increased risk of malignancy..

Mutagenesis

Colchicine was negative for mutagenicity in the bacterial reverse mutation assay. In a chromosomal aberration assay in cultured human white blood cells, colchicine treatment resulted in the formation of micronuclei. Since published studies demonstrated that colchicine induces aneuploidy from the process of mitotic nondisjunction without structural DNA changes, colchicine is not considered clastogenic, although micronuclei are formed.

Impairment of Fertility

No studies of colchicine effects on fertility were conducted with ColciGel®. However, published nonclinical studies demonstrated that colchicine-induced disruption of microtubule formation affects meiosis and mitosis. Reproductive studies also reported abnormal sperm morphology and reduced sperm counts in males, and interference with sperm penetration, second meiotic division, and normal cleavage in females when exposed to colchicine. Colchicine administered to pregnant animals resulted in fetal death and teratogenicity. These effects were dose dependent, with the timing of exposure critical for the effects on embryofetal development. The nonclinical doses evaluated were generally higher than an equivalent human **ORAL** therapeutic dose, but safety margins for reproductive and developmental toxicity could not be determined. Case reports and epidemiology studies in human male subjects on colchicine therapy indicated that infertility from colchicine is rare. A case report indicated that azoospermia was reversed when therapy was stopped. Case reports and epidemiology studies in female subjects on colchicine therapy have not established a clear relationship between colchicine use and female infertility. The use of colchicine needs to be weighed against the potential risks.

14 HOW SUPPLIED/STORAGE AND HANDLING

14.1 How Supplied

ColciGel® is Colchicine 4X in a transdermal gel base. The gel is viscous and opaque in appearance. ColciGel® is available in 2x15mL sealed dispensing containers that produce 0.25 mL of gel per each manual depression of the plunger top (pump).
2x15mL (1.01 fl oz) Bottles NDC 35781-0400-4

14.2 Storage

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

DISPENSE IN ORIGINAL CONTAINER.

US Patent Pending

Manufactured for:

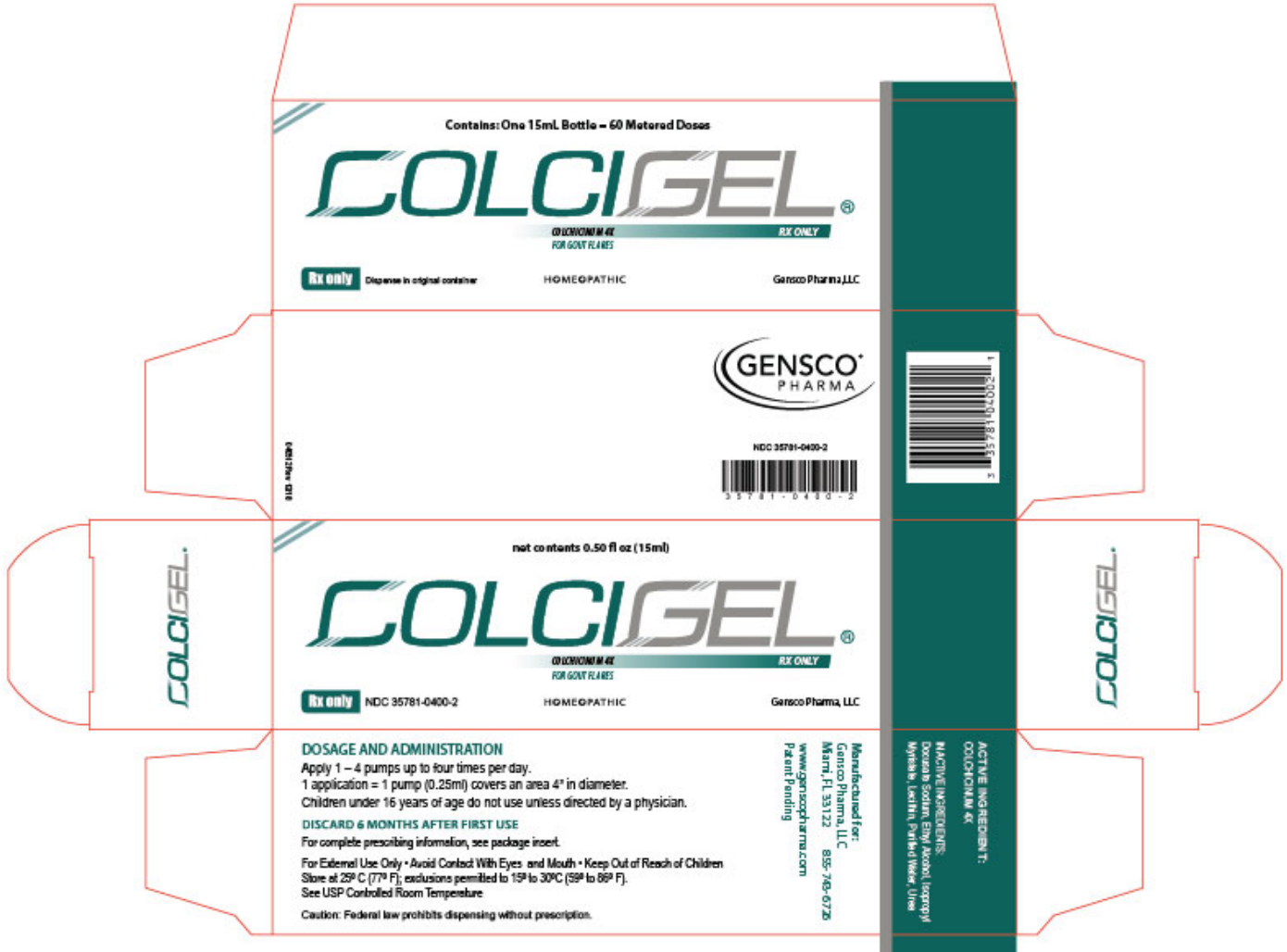
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HOMEOPATHIC
COLCIGEL[®]
 For Gout Flares

Active Ingredients: Colchicum 4X

DOSAGE AND ADMINISTRATION

Apply 1 – 4 pumps up to four times per day.
 1 application = 1 pump (0.25ml) covers an area 4" in diameter.
 Children under 16 years of age do not use unless directed by a physician.

Rx only net contents 0.50 fl oz (15ml)

For complete prescribing information, see package insert.

For External Use Only • Avoid Contact With Eyes and Mouth

Keep Out of Reach of Children

Store at 25° C (77° F); excursions permitted to 15° to 30°C (59° to 86° F).

See USP Controlled Room Temperature

Caution: Federal law prohibits dispensing without prescription.
 US Patent Pending

DISCARD 6 MONTHS AFTER FIRST USE

100114 Rev. 12/18

NDC 35781-0400-2



Manufactured for:
 Gensco Pharma, LLC | Miami, FL 33122
 855-743-6726 | www.genscopharma.com

COLCIGEL

colchicum 4x gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:35781-0400
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COLCHICINE (UNII: SML2Y3J35T) (COLCHICINE - UNII:SML2Y3J35T)	COLCHICINE	4 [hp_X] in 15 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
UREA (UNII: 8W8T17847W)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35781-0400-4	2 in 1 PACKAGE	05/01/2015	
1		30 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product		
2	NDC:35781-0400-2	1 in 1 CARTON	05/01/2015	

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15 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		05/01/2015	

Labeler - Gensco Laboratories, LLC (831042325)

Registrant - Gensco Laboratories, LLC (831042325)

Revised: 10/2022

Gensco Laboratories, LLC