

TRANZGEL - echinacea angustifolia, echinacea purpurea, aconitum napellus, arnica montana, calendula officianalis, hamamelis virginiana, belladonna, bellis perennis, chamomilla, millefolium, hypericum perforatum, symphytum officinale, colchicinum 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.

TRANZGEL HOMEOPATHIC TRANSDERMAL PAIN RELIEF GEL

ACTIVE INGREDIENTS:

ECHINACEA ANGUSTIFOLIA 1X HPUS, ECHINACEA PUPUREA 1X HPUS, ACONITUM NAPELLUS 3X HPUS, ARNICA MONTANA 3X HPUS, CALENDULA OFFICIANALIS 1X HPUS, HAMAMELIS VIRGINIANA 1X HPUS, BELLADONNA 3X HPUS, BELLIS PERENNIS 1X HPUS, CHAMOMILLA 1X HPUS, MILLEFOLIUM 1X HPUS, HYPERICUM PERFORATUM 6X HPUS, SYMPHYTUM OFFICINALE 4X HPUS, COLCHICINUM 3X HPUS

INACTIVE INGREDIENTS:

PURIFIED WATER, ISOPROPYL MYRISTATE, LECITHIN, UREA, DOCUSATE SODIUM, SODIUM HYDROXIDE

NDC 35781-0194-5

TRANZGEL

HOMEOPATHIC TRANSDERMAL PAIN RELIEF GEL

RX ONLY NET CONTENTS 1.7 FL OZ (50 ML)

GENSCO LABORATORIES, LLC

FOR COMPLETE PRESCRIBING INFORMATION, SEE PACKAGE INSERT. STORE AT ROOM TEMPERATURE.

MANUFACTURED BY FORMULATED SOLUTIONS

CLEARWATER, FL 33760

US PATENT #5,654,337

MANUFACTURED FOR GENSCO LABORATORIES, LLC

INVERNESS, FL 34452

352.726.6284

866.608.6284

WWW.TRANZGEL.COM

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ACTIVE INGREDIENTS:

ECHINACEA ANGUSTIFOLIA 1X HPUS, ECHINACEA PUPUREA 1X HPUS, ACONITUM
NAPELLUS 3X HPUS, ARNICA MONTANA 3X HPUS, CALENDULA OFFICIANALIS 1X HPUS,
HAMAMELIS VIRGINIANA 1X HPUS, BELLADONNA 3X HPUS, BELLIS PERENNIS 1X HPUS,
CHAMOMILLA 1X HPUS, MILLEFOLIUM 1X HPUS, HYPERICUM PERFORATUM 6X HPUS,
SYMPHYTUM OFFICINALE 4X HPUS, COLCHICINUM 3X HPUS

INACTIVE INGREDIENTS:

PURIFIED WATER, ISOPROPYL MYRISTATE, LECITHIN, UREA, DOCUSATE SODIUM,
SODIUM HYDROXIDE

For complete prescribing information, see package insert. Store at room temperature.

DESCRIPTION

A homeopathic topical analgesic gel that contains the active ingredients indicated below in the corresponding concentrations.

ACTIVE INGREDIENTS:

50 PARTS EACH: ECHINACEA ANGUSTIFOLIA 1X HPUS, ECHINACEA PUPUREA 1X HPUS,
30 PARTS: ACONITUM NAPELLUS 3X HPUS, 15 PARTS EACH: ARNICA MONTANA 3X HPUS,
CALENDULA OFFICIANALIS 1X HPUS, HAMAMELIS VIRGINIANA 1X HPUS, 10 PARTS:
BELLADONNA 3X HPUS, 5 PARTS EACH: BELLIS PERENNIS 1X HPUS, CHAMOMILLA 1X
HPUS, 3 PARTS MILLEFOLIUM 1X HPUS, 1 PART EACH: HYPERICUM PERFORATUM 6X
HPUS, SYMPHYTUM OFFICINALE 4X HPUS, .01 PART COLCHICINUM 3X HPUS

INACTIVE INGREDIENTS:

PURIFIED WATER, ISOPROPYL MYRISTATE, LECITHIN, UREA, DOCUSATE SODIUM,
SODIUM HYDROXIDE

Physical Information

PHYSICAL INFORMATION

A clear amber colored, viscous gel with a slight floral smell.

CLINICAL PHARMACOLOGY

According to traditional homeopathic literature and Material Medica, the following ingredients provide the following attributes:

INGREDIENTS	COMMON NAME	INDICATIONS
Arnica Montana	Mountain arnica	Stimulates healing of injured tissues wounds, contusions, hematomas, neuralgia myalgia, analgesia
Calendula Officinalis	Calendula	Inflammation
Hamamelis Virginiana	Witch-hazel	Analgesic
Millefolium	Yarrow	Hematomas
Belladonna	Banewort	Inflammation locally
Aconitum Napellus	Monk's hood	Neuralgia, rheumatism hemostasis, analgesia
Chamomilla	Chamomile	Inflammation, nausea
Colchicinum	Colchicine	Inflammation and gout
Symphytum Officinale	Comfrey	Neuropathy, contusions, tendonitis, arthritis
Bellis Perennis	Daisy	bruising, edema, arthralgia
Echinacea Angustifolia	Narrow leaf cone flower	Inflammation, myalgia
Echinacia purpurea	purple cone flower	Inflammation, myalgia
Hypericum perforatum	st. john's wort	neuropathic pains

INDICATIONS AND USAGE

The drug is indicated for the relief of symptoms, including pain and inflammation associated with arthritis or trauma (such as sprains, strains, dislocations, repetitive/overuse injuries, traumatic, edema, post surgical edema, hematoma, general swelling of joints and soft tissues) to areas such as hand, wrist elbow, shoulder, neck, back, knees, ankles, feet and toes.

CONTRAINDICATIONS

This drug should not be used by those sensitive to Arnica or any of the other listed ingredients.

WARNINGS AND PRECAUTIONS

For external use only. direct patient not to ingest TRANZEL and to avoid contact with they eyes, mucous membranes, wounds, and damaged skin. If a rash develops, patient should discontinue use until rash clears. After the disappearance of rash, patient can try TRANZGEL again on a test area and monitor

the site for additional results. If no rash or redness results, then patient can resume use. However, if the rash persists or redevelops, use should be discontinued.

Direct the patient to keep this product out of reach of children and seek medical help or contact a Poison Control Center immediately if swallowed.

In the homeopathic concentrations used to make TRANZGEL, there are no known or expected interactions with other drugs or laboratory tests. In addition, the homeopathic concentrations used are below any levels with known or suspected toxicities.

OVERDOSAGE

According to toxicology studies, a patient would have to orally ingest a minimum of 22 bottles of TRANZGEL to experience any initial toxic effects.

ADVERSE REACTIONS

Rarely, allergic skin reactions may occur. These effects are transient and will clear after a few days.

Apply a thin layer (1 drop covers an area of skin 2 inches by 2 inches) to the affected area 3-4 times daily and rub in gently. Applications of less than 3-4 times a day will not produce optimum results. Excess drops may be wiped from the area.

Package size: 1.7 fl oz (50 ml) airless pump dispensing bottle

US PATENT 5,654,337

NDC 35781-0194-5

STORE AT ROOM TEMPERATURE

Manufactured by

Formulated Solutions, LLC

Clearwater, FL 33760

Manufactured for

Gensco Laboratories, LLC

Inverness, FL 34452

352-726-6284

866-608-6284

www.tranzgel.com

ACTIVE INGREDIENTS:

Echinacea Angustifolia 1X HPUS, Echinacea Purpurea 1X HPUS, Aconitum Napellus 3X HPUS, Arnica Montana 3X HPUS, Calendula Officinalis 1X HPUS, Hamamelis Virginiana 1X HPUS, Belladonna 3X HPUS, Bellis Perennis 1X HPUS, Chamomilla 1X HPUS, Millefolium 1X HPUS, Hypericum Perforatum 6X HPUS, Symphytum Officinale 4X HPUS, Colchicinum 3X HPUS

INACTIVE INGREDIENTS:

Purified Water, Isopropyl Myristate, Lecithin, Urea, Docusate Sodium, Sodium Hydroxide

NDC 35781-0194-5



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Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:35781-0194
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ECHINACEA ANGUSTIFOLIA (UNII: VB06AV5US8) (ECHINACEA ANGUSTIFOLIA - UNII:VB06AV5US8)	ECHINACEA ANGUSTIFOLIA	1 [hp_X] in 50 mL
ECHINACEA PURPUREA (UNII: QI7G114Y98) (ECHINACEA PURPUREA - UNII:QI7G114Y98)	ECHINACEA PURPUREA	1 [hp_X] in 50 mL
ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	3 [hp_X] in 50 mL
ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	3 [hp_X] in 50 mL
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	1 [hp_X] in 50 mL
HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK (UNII: T7S323PKJS)	HAMAMELIS VIRGINIANA	1 [hp_X]

(HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK - UNII:T7S323PKJS)	ROOT BARK/STEM BARK	in 50 mL
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	3 [hp_X] in 50 mL
BELLIS PERENNIS (UNII: 2HU33I03UY) (BELLIS PERENNIS - UNII:2HU33I03UY)	BELLIS PERENNIS	1 [hp_X] in 50 mL
CHAMOMILE (UNII: FGL3685T2X) (CHAMOMILE - UNII:FGL3685T2X)	CHAMOMILE	1 [hp_X] in 50 mL
ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK) (ACHILLEA MILLEFOLIUM - UNII:2FXJ6SW4PK)	ACHILLEA MILLEFOLIUM	1 [hp_X] in 50 mL
HYPERICUM OIL (UNII: OZU2FC70HY) (HYPERICUM OIL - UNII:OZU2FC70HY)	HYPERICUM OIL	6 [hp_X] in 50 mL
COMFREY ROOT (UNII: M9VVZ08EKQ) (COMFREY ROOT - UNII:M9VVZ08EKQ)	COMFREY ROOT	4 [hp_X] in 50 mL
COLCHICINE (UNII: SML2Y3J35T) (COLCHICINE - UNII:SML2Y3J35T)	COLCHICINE	3 [hp_X] in 50 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
UREA (UNII: 8W8T17847W)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35781-0194-5	1 in 1 CARTON		
1		50 mL in 1 BOTTLE, DISPENSING		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		07/01/2010	

Labeler - Gensco Laboratories, LLC (831042325)

Establishment

Name	Address	ID/FEI	Business Operations
Formulated Solutions		143266687	manufacture