

TRANZGEL - echinacea angustifolia, echinacea purpurea, aconitum napellus, arnica montana, calendula officianalis, hamamelis virginiana, belladonna, bellis perennis, chamomillia, millefolium, hypericum perforatum, symphytum officinale, colchicinum gel
Unit Dose Services

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

TRANZGEL (ECHINACEA ANGUSTIFOLIA, ECHINACEA PURPUREA, ACONITUM NAPELLUS, ARNICA MONTANA, CALENDULA OFFICIANALIS, HAMAMELIS VIRGINIANA, BELLADONNA, BELLIS PERENNIS, CHAMOMILLIA, MILLEFOLIUM, HYPERICUM PERFORATUM, SYMPHYTUM OFFICINALE, COLCHICINUM) GEL

NDC: 50436-9071-1			
TRANZGEL			
TRANSDERMAL PAIN RELIEF			
GEL			
50 ML	MFG FOR: GENSCO LABS, LLC MIRAMAR, FL 33027		
WARNING: KEEP OUT OF REACH OF CHILDREN. STORE AT 25 C (77 F) CONTROLLED ROOM TEMPERATURE.SEE PACKAGE INSERT FOR DOSAGE INFORMATION.	MFG NDC: 35781-0194-5 MFG LOT: XXXXX LOT: XXXXX EXP: XXXXX		
	Pkg by: Unit Dose Services, LLC Dania, FL 33004		
			NDC: 50436-9071-1 50 ML DRUG: TRANZGEL GEL TRANSDERMAL PAIN RELIEF LOT: XXXXX EXP: XXXXX
			NDC: 50436-9071-1 50 ML DRUG: TRANZGEL GEL TRANSDERMAL PAIN RELIEF LOT: XXXXX EXP: XXXXX
			NDC: 50436-9071-1 50 ML DRUG: TRANZGEL GEL TRANSDERMAL PAIN RELIEF LOT: XXXXX EXP: XXXXX

MANUFACTURED BY
FORMULATED SOLUTIONS, LLC
CLEARWATER FL 33760
US PATENT #5,654,337

MANUFACTURED BY
GENSCO LABORATORIES, LLC
INVERNESS, FL 34452

352.726.6284

866.608.6284

WWW.TRANZGEL.COM

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.

Calendula Officianalis	Calendula	Inflammation	Hamamelis Virginiana	Witch-hazel
Belladonna	Analgesic Millefolium	Yarrow	Hematomas	
Monk's hood	Banewort	Inflammation locally	Aconitum Napellus	
Chamomile	Neuralgia, rheumatism	hemostasis, analgeisa	Chamomilla	
Inflammation and gout	Inflammation, nausea	Colchicinum	Colchicine	
tendonitis, arthritis	Symphytum Officinale	Comfrey	Neuropathy, contusions,	
Echinacea Angustifolia	Bellis Perennis	Daisy	brusing, edema, arthralgia	
purple cone flower	Narrow leaf cone flower	Inflammation, myalgia	Echinacia purpurea	
neuropathic pains	Inflammation, myalgia	Hypericum perforatum	st. john's wort	

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

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 their 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.

NDC:50436-9071-1 in a BOTTLE of 50 GELS

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

TRANZGEL

echinacea angustifolia, echinacea purpurea, aconitum napellus, arnica montana, calendula officianalis, hamamelis virginiana, belladonna, bellis perennis, chamomillia, millefolium, hypericum perforatum, symphytum officinale, colchicium gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:50436-9071(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 ROOT BARK/STEM BARK - UNII:T7S323PKJS)	HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK	1 [hp_X] 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:50436-9071-1	50 mL in 1 BOTTLE		

Marketing Information

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

Labeler - Unit Dose Services (831995316)

Registrant - Unit Dose Services (831995316)

Establishment

Name	Address	ID/FEI	Business Operations
Unit Dose Services		831995316	REPACK(50436-9071)

Revised: 9/2010

Unit Dose Services