

SPEEDGEL RX- echinacea angustifolia, echinacea purpurea, aconitum napellus, arnica montana, calendula officinalis, hamamelis virginiana, belladonna, bellis perennis, chamomilla, millefolium, hypericum perforatum, symphytum officinale, colchicinum, zingiber officinale 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.

SPEEDGEL RX

TOPICAL ANTI-INFLAMMATORY/ANALGESIC

DESCRIPTION

SpeedGel Rx® is a prescription transdermal gel that provides relief of pain, inflammation and bruising, utilizing patented Isopeutic™ Transdermal Technology. The Gensco® patented transdermal drug delivery system used in SpeedGel Rx® carries proprietary formulation of active ingredients, through the skin to the locally affected tissues. SpeedGel Rx® is applied directly to the affected site specifically, minimizing side effects, interactions and comorbidities caused by oral therapies and topical NSAIDs. Furthermore, SpeedGel Rx® is clinically proven to reduce narcotic use.

SpeedGel Rx® is indicated for the relief of pain, inflammation and bruising from musculoskeletal pain and associated inflammation, inflammatory conditions of joints and soft tissues, arthritis, injuries such as sprains, strains, and dislocations, repetitive/overuse injuries, general aches and pains, contusions and trauma to such areas as hands, wrist, elbow, shoulder, neck, back, knees, ankles, feet and toes. SpeedGel Rx® is a proprietary combination of 14 active ingredients, 4 of which are prescription, in a patented transdermal delivery system. Among the prescription ingredients is Colchicinum Autumnale also known as Colchicine, which is a well-known, strong and effective anti-inflammatory medication.

It contains the following **active ingredients**:

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

It also contains the following **inactive ingredients**:

Docusate sodium, Ethyl Alcohol, Isopropyl myristate, Lecithin, Purified

Water & Urea.

The patented transdermal gel's liposomal base comprising of hydrophilic and lipophilic components is designed to suspend the active ingredients and allow for the hydration of the skin barrier and movement of the active ingredients, irrespective of their molecular polarity, across the skin at an enhanced rate. The unique transdermal characteristics in SpeedGel Rx® permit the active ingredients to penetrate to the site of injury, diminishing pain and inflammation, and enhancing bruise resolution. As a topically applied transdermal medication, SpeedGel Rx® avoids the common concerns of toxicity and drug interactions associated with systemic (oral) medications.

SpeedGel Rx® is an amber colored, odorless gel dispensed in a patented metered dose container (MDose) containing either 10ml, 30ml, or 90ml. Gensco's unique metered dose technology (MDose™) which dispenses exactly (0.25 mL of medication per pump) per application, covering a 2"x2" area of skin. MDose provides more accurate dosing, less waste and significant cost savings (Gensco® Pharma Tube vs. Pump Study).

CLINICAL PHARMACOLOGY

SpeedGel Rx® is a drug under FDA regulation and HPUS monograph. The active ingredients of SpeedGel Rx® are listed and described within the Homeopathic Pharmacopeia of the United States (HPUS), the official FDA compendium of homeopathic drugs.

The Homeopathic Pharmacopeia of the United States (HPUS), the officially recognized FDA reference source for homeopathic compounds in the U.S., identifies the ingredients of SpeedGel Rx® as shown in TABLE 1.:

Ingredients	Common Name	Indications
Aconitum Napellus	Monk's-hood	Neuralgia, rheumatism, hemostasis, analgesia
Arnica Montana	Mountain arnica	Stimulates healing of injured tissues, wounds, contusions, hematomas, neuralgia, myalgia, analgesia
Belladonna	Deadly nightshade	Inflammation locally
Bellis Perennis	Daisy	Dislocations, bruising, reducing edema
Calendula Officinalis	Calendula	Analgesia, inflammation
Colchicinum	Colchicine	Inflammation and gout
Chamomilla	Chamomile	Inflammation, promotes healing of tissues
Echinacea Angustifolia	Narrow leaf cone flower	Inflammation and inhibits hyaluronidase
Echinacea Purpurea	Purple cone flower	Stimulates fibroblasts, inflammation
Hamamelis Virginiana	Witch-hazel	Astringent, analgesic, hematomas

Hypericum Perforatum	St. John's wort	Neuropathic pains
Millefolium	Yarrow	Hematomas, wound healing
Symphytum Officinale	Comfrey	Neuropathy, causalgia, contusions, periostitis
Zingiber Officinale	Ginger	Inflammation

Bolded items are at strengths recognized by the HPUS as requiring a prescription.

INDICATIONS AND USAGE

SpeedGel Rx® is indicated for the relief of pain, inflammation and bruising from musculoskeletal pain and associated inflammation, inflammatory conditions of joints and soft tissues, arthritis, injuries such as sprains, strains, and dislocations, repetitive/overuse injuries, general aches and pains, contusions and trauma to such areas as hands, wrist, elbow, shoulder, neck, back, knees, ankles, feet and toes.

CONTRAINDICATIONS

Known sensitivity to any of the active or inactive ingredients of SpeedGel Rx®.

WARNINGS

For external use only. Direct patient not to ingest SPEEDGEL RX and to avoid contact with the eyes and mucous membranes, wounds, and damaged skin. If condition worsens, or if symptoms persist for more than seven days or clear up and occur again within a few days, patient should consult a doctor. If a rash develops, patient should discontinue use until rash clears. After the disappearance of rash, patient can try SPEEDGEL RX 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 patient to keep this product out of reach of children and seek medical help or contact a Poison Control Center immediately if swallowed.

PRECAUTIONS

Use in Pregnancy: No human or animal studies on the effect of SPEEDGEL RX in pregnancy have been conducted.

Nursing Mothers: It is not known whether SPEEDGEL RX is excreted in breast milk.

FEMALES & MALES OF REPRODUCTIVE POTENTIAL

No human or animal studies on the effect of SpeedGel Rx® in females & males of reproductive potential have been conducted.

ADVERSE REACTIONS

Rarely, allergic skin reactions may occur. If allergic reactions occur, discontinue use of the drug.

DOSAGE AND ADMINISTRATION

Apply 1 ml (4 pumps of the bottle) as a thin layer to the affected area 3-4 times daily and rub in gently (wash hands after application). Applications of less than 3-4 times daily will not produce optimum results. Excess amounts may be wiped from the area. Safe to use on children over the age of 2 years.

Applications of less than 3-4 times a day will not produce optimum results. Excess drops may be wiped from the area.

HOW SUPPLIED/STORAGE AND HANDLING

NDC 35781-0210-1 HOMEOPATHIC TRANSDERMAL PAIN RELIEF GEL RX ONLY NET CONTENTS 0.33 FL OZ (10 ML) Package Size: 0.33 fl oz (10ml) bottle
NDC 35781-0210-2 HOMEOPATHIC TRANSDERMAL PAIN RELIEF GEL RX ONLY NET CONTENTS 1.01 FL OZ (30 ML) Package Size: 1.01 fl oz (30ml) bottle
NDC 35781-0210-9 HOMEOPATHIC TRANSDERMAL PAIN RELIEF GEL RX ONLY NET CONTENTS 3.04 FL OZ (90 ML) Package Size: 3.04 fl oz (90ml) bottle
Manufactured for: Gensco Pharma, LLC
8550 NW 33rd Street, Suite 200. Miami, FL 33122 (855) 743-6726
www.genscopharma.com

SPEED GEL[®] RX

TOPICAL ANTI-INFLAMMATORY/ANALGESIC

Rx only net contents .33 fl oz (10ml) HOMEOPATHIC Genco Pharma, LLC

Manufactured for:
Genco Pharma, LLC
Miami, FL 33122
855-743-6726
www.gencopharma.com



NDC 35781-0210-1



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Caution: Federal law prohibits dispensing without prescription
Dispense in original container



SPEED GEL[®] RX
TOPICAL ANTI-INFLAMMATORY/ANALGESIC

SPEED GEL[®] RX

TOPICAL ANTI-INFLAMMATORY/ANALGESIC

Rx only net contents 0.33 fl oz (10ml) HOMEOPATHIC Genco Pharma, LLC

NDC 35781-0210-1

DOSAGE AND ADMINISTRATION

Apply 1 ml (4 pumps of the bottle) as a thin layer to the affected area 3-4 times daily and rub in gently (wash hands after application). Applications of less than 3-4 times daily will not produce optimum results. Excess amounts may be wiped from the area. Safe to use on children over the age of 2 years.

INDICATIONS AND USAGE

Indicated for the relief of pain, inflammation and bruising from musculoskeletal pain and associated inflammation, inflammatory conditions of joints and soft tissues, arthritis, injuries such as sprains, strains, and dislocations, repetitive/overuse injuries, general aches and pains, contusions and trauma to such areas as hands, wrist, elbow, shoulder, neck, back, knees, ankles, feet and toes.

For complete prescribing information, see package insert.

For External Use Only - Avoid Contact With Eyes - 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

INACTIVE INGREDIENTS:

Dozusate Sodium, Ethyl Alcohol, Isopropyl Myristate, Lecithin, Purified Water & Urea.

HOMEOPATHIC

Aconitum Napellus 3X
Amica Montana 1X
Belladonna 3X
Bellis Perennis 1X
Calendula Officinalis 1X
Chamomilla 1X
Colchicum 3X
Echinacea Angustifolia 1X
Echinacea Purpurea 1X
Hamamelis Virginiana 1X
Hypericum Perforatum 1X
Millefolium 1X
Symphytum Officinale 3X
Zingiber Officinale 1X

Patented Isopeutic™ Transdermal Technology

SPEED GEL[®] RX

TOPICAL ANTI-INFLAMMATORY/ANALGESIC

Rx only net contents 1.01 fl oz (30ml)

HOMEOPATHIC

GenSCO Pharma, LLC

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



NDC 35781-0210-2



35781-0210-2

6180 / 762 02100

Caution: Federal law prohibits dispensing without prescription
Dispense in original container

Patented Isopeutic™ Transdermal Technology

SPEED GEL[®] RX

TOPICAL ANTI-INFLAMMATORY/ANALGESIC

Rx only net contents 1.01 fl oz (30ml)

HOMEOPATHIC

GenSCO Pharma, LLC

NDC 35781-0210-2

SPEED GEL[®] RX
TOPICAL ANTI-INFLAMMATORY/ANALGESIC

DOSAGE AND ADMINISTRATION

Apply 1 ml (4 pumps of the bottle) as a thin layer to the affected area 3-4 times daily and rub in gently (wash hands after application). Applications of less than 3-4 times daily will not produce optimum results. Excess amounts may be wiped from the area. Safe to use on children over the age of 2 years.

INDICATIONS AND USAGE

Indicated for the relief of pain, inflammation and bruising from musculoskeletal pain and associated inflammation, inflammatory conditions of joints and soft tissues, arthritis, injuries such as sprains, strains, and dislocations, repetitive/overuse injuries, general aches and pains, contusions and trauma to such areas as hands, wrist, elbow, shoulder, neck, back, knees, ankles, feet and toes.

For complete prescribing information, see package insert.
For External Use Only • Avoid Contact With Eyes • 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

INACTIVE INGREDIENTS:

Docusate Sodium, Ethyl Alcohol, Isopropyl Myristate, Lecithin, Purified Water & Urea.

HOMEOPATHIC
Aconitum Napellus 3X
Arnica Montana 1X
Belladonna 3X
Bellis Perennis 1X
Calendula Officinalis 1X
Chamomilla 1X
Coccyzus 3X
Echinacea Angustifolia 1X
Echinacea Purpurea 1X
Hamamelis Virginiana 1X
Hypericum Perforatum 1X
Millefolium 1X
Symphytum Officinale 3X
Zingiber Officinale 1X

SPEED GEL[®]

TOPICAL ANTI-INFLAMMATORY/ANALGESIC

Rx only net contents 3.04 fl oz (90ml) HOMEOPATHIC GenSCO Pharma, LLC

Manufactured for:
GenSCO Pharma, LLC
Miami, FL 33122
855-743-0726
www.geniscopharma.com



01/16/16/15/090

Caution: Federal law prohibits dispensing without prescription
Dispense in original container

SPEED GEL[®]

TOPICAL ANTI-INFLAMMATORY/ANALGESIC

Rx only net contents 3.04 fl oz (90ml) HOMEOPATHIC GenSCO Pharma, LLC

NDC 35781-0219-9

DOSAGE AND ADMINISTRATION

Apply 1 ml (4 pumps of the bottle) as a thin layer to the affected area 3-4 times daily and rub in gently (wash hands after application). Applications of less than 3-4 times daily will not produce optimum results. Excess amounts may be wiped from the area. Safe to use on children over the age of 2 years.

INDICATIONS AND USAGE

Indicated for the relief of pain, inflammation and bruising from musculoskeletal pain and associated inflammation, inflammatory conditions of joints and soft tissues, arthritis, injuries such as sprains, strains, and dislocations, repetitive/overuse injuries, general aches and pains, contusions and trauma to such areas as hands, wrist, elbow, shoulder, neck, back, knees, ankles, feet and toes.

For complete prescribing information, see package insert.
For External Use Only - Avoid Contact With Eyes - 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

INACTIVE INGREDIENTS:
Dicazate Sodium, Ethyl Alcohol, Isopropyl Myristate, Lecithin, Purified Water & Urea.

HOMEOPATHIC
Aconitum Napellus 3X
Arnica Montana 1X
Belladonna 3X
Bellis Perennis 1X
Ceanothus Officinalis 1X
Chamaemelum 1X
Coccoloba 3X
Echinacea Angustifolia 1X
Echinacea Purpurea 1X
Hamamelis Virginiana 1X
Hypericum Perforatum 1X
Mullein 1X
Symphytum Officinale 3X
Zingiber Officinale 1X

SPEED GEL[®]

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DOSAGE AND ADMINISTRATION

Apply 1 ml (4 pumps of the bottle) as a thin layer to the affected area 3-4 times daily and rub in gently (wash hands after application). Applications of less than 3-4 times daily will not produce optimum results. Excess amounts may be wiped from the area. Safe to use on children over the age of 2 years.

INDICATIONS AND USAGE

Indicated for the relief of pain, inflammation and bruising from musculoskeletal pain and associated inflammation, inflammatory conditions of joints and soft tissues, arthritis, injuries such as sprains, strains, and dislocations, repetitive/overuse injuries, general aches and pains, contusions and trauma to such areas as hands, wrist, elbow, shoulder, neck, back, knees, ankles, feet and toes.

Rx only net contents 1.01 fl oz (30ml)

For complete prescribing information, see package insert.
 For External Use Only • Avoid Contact With Eyes • Keep Out of Reach of Children
 Store at 25° C (77° F); exclusions permitted to 15° to 30°C (59° to 86° F).
 See USP Controlled Room Temperature

Caution: Federal law prohibits dispensing without prescription

HOMEOPATHIC

Active Ingredients

Aconitum Napellus 3X, Arnica Montana 1X, Belladonna 3X, Bellis Perennis 1X, Calendula Officinalis 1X, Chamomilla 1X, Colchicium 3x, Echinacea Angustifolia 1X, Echinacea Purpurea 1X, Hamamelis Virginiana 1X, Hypericum Perforatum 1X, Montana 1X, Millefolium 1X, Symphytum Officinale 3X, Zingiber Officinale 1X

Inactive Ingredients

Docusate sodium, Isopropyl myristate, Lecithin, Purified water, Sodium hydroxide, Urea



Manufactured for:
 Gensco Pharma, LLC | Miami, FL 33122
 855-743-6726

www.genscopharma.com

04/05/12 Rev. 04/19

NDC 35781-0210-2

SPEEDGEL RX

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

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:35781-0210
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 30 mL
ECHINACEA PURPUREA (UNII: QI7G114Y98) (ECHINACEA PURPUREA - UNII:QI7G114Y98)	ECHINACEA PURPUREA	1 [hp_X] in 30 mL
ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	3 [hp_X] in 30 mL
ARNICA MONTANA (UNII: O80TY208Z W) (ARNICA MONTANA - UNII:O80TY208Z W)	ARNICA MONTANA	1 [hp_X] in 30 mL
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	1 [hp_X] in 30 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 30 mL
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	3 [hp_X]

UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	in 30 mL
BELLIS PERENNIS (UNII: 2HU33I03UY) (BELLIS PERENNIS - UNII:2HU33I03UY)	BELLIS PERENNIS	1 [hp_X] in 30 mL
CHAMOMILE (UNII: FGL3685T2X) (CHAMOMILE - UNII:FGL3685T2X)	CHAMOMILE	1 [hp_X] in 30 mL
ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK) (ACHILLEA MILLEFOLIUM - UNII:2FXJ6SW4PK)	ACHILLEA MILLEFOLIUM	1 [hp_X] in 30 mL
HYPERICUM OIL (UNII: OZU2FC70HY) (HYPERICUM OIL - UNII:OZU2FC70HY)	HYPERICUM OIL	1 [hp_X] in 30 mL
COMFREY ROOT (UNII: M9VVZ08EKQ) (COMFREY ROOT - UNII:M9VVZ08EKQ)	COMFREY ROOT	3 [hp_X] in 30 mL
COLCHICINE (UNII: SML2Y3J35T) (COLCHICINE - UNII:SML2Y3J35T)	COLCHICINE	3 [hp_X] in 30 mL
GINGER (UNII: C5529G5JPQ) (GINGER - UNII:C5529G5JPQ)	GINGER	1 [hp_X] in 30 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
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:35781-0210-2	1 in 1 CARTON	12/01/2011	
1		30 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product		
2	NDC:35781-0210-1	1 in 1 CARTON	12/01/2011	
2		10 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product		
3	NDC:35781-0210-9	1 in 1 CARTON	12/01/2011	
3		90 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		12/01/2011	

Labeler - Gensco Laboratories, LLC (831042325)

Registrant - Gensco Laboratories, LLC (831042325)

Establishment

Name	Address	ID/FEI	Business Operations
All Pharma LLC		117605075	manufacture(35781-0210)

Revised: 10/2022

Gensco Laboratories, LLC