

**RAPID GEL RX- echinacea angustifolia, echinacea purpurea, aconitum napellus, arnica montana, calendula officinalis, hamamelis virginiana, belladonna, bellis perennis, chamomilla, millefolium, hypericum perforatum, symphytum officinale, colchicum, zingiber officinale gel TMIG Inc**

*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.*

**Rapid Gel Rx**

**TOPICAL ANTI-INFLAMMATORY HOMEOPATHIC ANALGESIC**

**DESCRIPTION**

Rapid Gel Rx is a homeopathic topical analgesic gel that contains the ingredients listed below. Homeopathic ingredients have been used since the inception of this science and remain as an effective method of treating select conditions. It is a white colored odorless gel for use externally to control inflammation and reduce pain.

**It contains the following active ingredients:**

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

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

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

**CLINICAL PHARMACOLOGY**

The exact pharmacology by which Rapid Gel RX works to control aches and pains 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 such areas as hands, wrist, elbow, shoulder, neck, back, knees, ankles, feet and toes is unknown. It is theorized that, according to traditional homeopathy, the following ingredients contribute in the following ways:

<b>Ingredients</b>	<b>Common Name</b>	<b>Indications</b>
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
Colchicum	Colchicine	Inflammation and gout
Chamomilla	Chamomile	Inflammation, promotes healing of tissues
Echinacea Angustifolia	Narrow leaf cone flower	Inflammation and inhibits

Echinacea Angustifolia	Narrow leaf cone flower	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

## INDICATIONS AND USAGE

Rapid Gel RX is indicated for the relief of pain and inflammation from: arthritis or injuries such as sprains, strains, dislocations, repetitive/overuse injuries, traumatic edema, post-surgical edema, general swelling of joints and soft tissues of the hand, wrist, elbow, shoulder, neck, back, knee, ankle, foot and toe and general aches and pains.

## CONTRAINDICATIONS

Known sensitivity to Arnica Montana or any other ingredient.

## PRECAUTIONS

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

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

## ADVERSE REACTIONS

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

## DOSAGE AND ADMINISTRATION

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.

## HOW SUPPLIED/STORAGE AND HANDLING

NDC 69176-070-30

HOMEOPATHIC TRANSDERMAL PAIN RELIEF GEL

RX ONLY NET CONTENTS 30g

NDC 69176-070-90

HOMEOPATHIC TRANSDERMAL PAIN RELIEF GEL

RX ONLY NET CONTENTS 90g

**Manufactured for:**

TMIG Inc.  
Marietta, GA

## **WARNINGS**

For external use only. Direct patient not to ingest Rapid Gel 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 Rapid Gel 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.

# RAPID GEL RX

NDC 69176 070-30



Anti-inflammation Homeopathic gel

Net Wt 30g. For external use only



Federal Law prohibits dispensing without a prescription

# RAPID GEL RX

Anti-inflammation Homeopathic gel

**PHARMACIST:** Dispense all enclosed patient information leaflets to patient.  
**WARNING:** Keep out of reach of children  
Store in cool dry place at 20-25 C (68 to 77 F)  
**DOSAGE:** Usual adult dosage, apply 2-3 times a day or as directed by your physician. See Package insert for full Prescribing Information.

Manufactured for and Distributed By: TMIG Inc.  
"Rapid Gel Rx" is a pending trademark of TMIG Inc



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**ACTIVE INGREDIENTS**

echinacea angustifolia, echinacea purpurea, aconitum napellus, arnica montana, calendula officinalis, hamamelis virginiana, belladonna, bellis perennis, chamomilla, millefolium, hypericum perforatum, symphytum officinale, colchicum, zingiber officinale gel

NET WT. 30g

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Rapid Gel Rx



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### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:69176-070
<b>Route of Administration</b>	TRANSDERMAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ECHINACEA ANGUSTIFOLIA</b> (UNII: VB06AV5US8) (ECHINACEA ANGUSTIFOLIA - UNII:VB06AV5US8)	ECHINACEA ANGUSTIFOLIA	1 [hp_X] in 30 mL
<b>ECHINACEA PURPUREA</b> (UNII: QI7G114Y98) (ECHINACEA PURPUREA - UNII:QI7G114Y98)	ECHINACEA PURPUREA	1 [hp_X] in 30 mL
<b>ACONITUM NAPELLUS</b> (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	3 [hp_X] in 30 mL
<b>ARNICA MONTANA</b> (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	1 [hp_X] in 30 mL
<b>CALENDULA OFFICINALIS FLOWERING TOP</b> (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	1 [hp_X] in 30 mL
<b>HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK</b> (UNII: T7S323PKJS) (HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK - UNII:T7S323PKJS)	HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK	1 [hp_X] in 30 mL
<b>ATROPA BELLADONNA</b> (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	3 [hp_X] in 30 mL
<b>BELLIS PERENNIS</b> (UNII: 2HU33I03UY) (BELLIS PERENNIS - UNII:2HU33I03UY)	BELLIS PERENNIS	1 [hp_X] in 30 mL
<b>CHAMOMILE</b> (UNII: FGL3685T2X) (CHAMOMILE - UNII:FGL3685T2X)	CHAMOMILE	1 [hp_X] in 30 mL
<b>ACHILLEA MILLEFOLIUM</b> (UNII: 2FXJ6SW4PK) (ACHILLEA MILLEFOLIUM - UNII:2FXJ6SW4PK)	ACHILLEA MILLEFOLIUM	1 [hp_X] in 30 mL
<b>HYPERICUM OIL</b> (UNII: OZU2FC70HY) (HYPERICUM OIL - UNII:OZU2FC70HY)	HYPERICUM OIL	1 [hp_X] in 30 mL
<b>COMFREY ROOT</b> (UNII: M9VVZ08EKQ) (COMFREY ROOT - UNII:M9VVZ08EKQ)	COMFREY ROOT	3 [hp_X] in 30 mL
<b>COLCHICINE</b> (UNII: SML2Y3J35T) (COLCHICINE - UNII:SML2Y3J35T)	COLCHICINE	3 [hp_X] in 30 mL
<b>GINGER</b> (UNII: C5529G5JPQ) (GINGER - UNII:C5529G5JPQ)	GINGER	1 [hp_X] in 30 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>UREA</b> (UNII: 8W8T17847W)	
<b>DOCUSATE SODIUM</b> (UNII: F05Q2T2JA0)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69176-070-30	1 in 1 CARTON	04/20/2016	
1		30 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69176-070-90	1 in 1 CARTON	04/20/2016	
2		90 mL in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		04/20/2016	

**Labeler** - TMIG Inc (036572986)

**Registrant** - TMIG Inc (036572986)

### Establishment

Name	Address	ID/FEI	Business Operations
Pocono coated products, LLC		362785771	manufacture(69176-070)

Revised: 5/2016

TMIG Inc