SPEEDGEL Rx®
TOPICAL ANTI-INFLAMMATORY/ANALGESIC

10ml: NDC 35781-0210-1
30ml: NDC 35781-0210-2
90ml: NDC 35781-0210-9

0.33 fl oz (10mL) bottle NDC 35781-0210-1
1.01 fl oz (30mL) bottle NDC 35781-0210-2
3.04 fl oz (90mL) bottle NDC 35781-0210-9

READ THIS INFORMATION BEFORE PRESCRIBING THIS PRODUCT

DESCRIPTION OF SpeedGel Rx®

SpeedGel Rx® is a prescription transdermal gel that provides relief of pain, inflammation and bruising, utilizing patented Isopeutic™ Transdermal Technology, US Patent #5,6545337. 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 disclocations, 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.**:

The mechanisms of action of several of the ingredients in SpeedGel Rx® have been described in clinical literature. Most notably, Colchicinium Autumnale has been shown to bind to tubulin in the cytoplasm of neutrophils causing the deformation of microtubules leading to the inhibition of the production of inflammatory mediators and chemotaxins thereby muting the inflammatory process.[1] Though Colchicinium Autumnale is commonly used as an oral drug in the treatment of the inflammation associated with acute gout flares, the gastrointestinal adverse effects and potential for life threatening toxicity commonly seen with the oral (systemic) formulations, has limited its use in other inflammatory conditions. Colchicinium Autumnale, as formulated in SpeedGel Rx®, does not share the adverse drug effects associated with the oral (systemic) preparations of colchicine.

Constituents of Arnica Montana, especially sesquiterpene lactones, has been shown to have mitigating effects on inflammation[2] and bruising[3]. The European Medicines Agency noted in their assessment of Arnica Montana, that the formulation and topical vehicle used had great impact on skin penetration and therefore, clinical effects seen.

Atropa Belladonna extract which, besides being a potent muscarinic antagonist, has been shown to shorten the process of acute inflammation as well as increasing tensile strength and collagen deposition in healing skin wounds.[4] In a study assessing the effects of Belladonna on wound healing, the authors concluded that Belladonna's effect is probably based on the acceleration of several processes occurring during wound healing. In particular, Belladonna is able to stimulate extracellular matrix production, endothelial cells proliferation and may indicate accelerated angiogenesis, and has anti-inflammatory effects.[5]

Calendula Officialis has been shown to increase wound healing. In a study evaluating the use of Calendula in venous leg ulcers, the authors noted the treatment group exhibited significantly improved wound healing compared to the placebo group.[6] Another study evaluating the use of Calendula in 2nd and 3rd degree burns concluded that the Calendula treatment group was better tolerated and demonstrated significantly greater wound healing that the standard treatment groups.[7]

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
Chamomilla	Chamomile	Inflammation, promotes healing of tissues
Colchicinum	Colchicine	Inflammation and gout
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.

Clinical trials evaluating SpeedGel Rx®:

A Randomized, Double-Blind, Clinical Study to Evaluate the Safety and Efficacy of SpeedGel Rx® in the Symptomatic Treatment of Osteoarthritis in the Interphalangeal Joints

This study evaluated the efficacy of SpeedGel Rx® for the treatment of Osteoarthritis of the Interphalangeal joints. In a two-week, randomized, double-blind, placebo-controlled, parallel-group trial, SpeedGel Rx® was administered at a dose of four times daily on the treatment hand. Pain was assessed using a 10-point visual analog scale. The reliability of the scale has been demonstrated in multiple studies.

Results:

1. By day two pain was lower in the treatment group than the control group.
2. By day five pain was over 10% lower in the treatment group.
3. Overall a 60% reduction in pain was found between the treatment group from baseline.
4. No subject in the treatment group reported a side effect.
5. A majority of subjects in the treatment group were taking some type of blood thinner.

Accelerated Resolution of Laser-Induced Bruising with SpeedGel Rx®

A Rater-Blinded Randomized Controlled Trial

The study's primary aims were: (1) to determine the effectiveness of SpeedGel Rx® in the reduction of pain in laser induced bruising over time, (2) to determine the effectiveness of SpeedGel Rx® in the change of appearance of the bruise over time, and (3) to determine the effectiveness of SpeedGel Rx® in the reduction of pigmented lesions that are monitored via a VISIA™ complexion analysis tool over time.

Results demonstrate that SpeedGel Rx® reduced pain more quickly than placebo. On day two subjects were 6% more likely to experience pain using the placebo gel than SpeedGel Rx®. This increased to 15% at day four. SpeedGel Rx® also improved the appearance of the bruise more quickly than placebo. Subjects indicated a 10% quicker resolution in the color and appearance of the bruise using SpeedGel Rx®.

Prospective Project to Determine the Efficacy of Prescription SpeedGel Rx® in Decreasing Post-Operative Surgical Site Pain and Narcotic Use

James R. Andrews M.D., Filippo Chillemi M.D., Mary Jane Robinson

A prospective study evaluating SpeedGel Rx®, a prescription homeopathic topical analgesic gel, in decreasing post-operative surgical site and overall narcotic use.

Subjectively, all patients have had positive remarks concerning SpeedGel Rx® with all stating that it was beneficial in both decreasing post-operative pain and narcotic use.

Objectively, positive results have also been noted. The majority of patients, (9/13) had not used SpeedGel Rx® on POD4, however by 1 week post-op, 92% compliance was achieved (12/13). Pain scores were obtained on post-op day 4, post-op weeks 1-4, and post-op week 6. The average pain scores were 3.60, 2.58, 1.89, 0.88, 1.13, and 0.83, respectively. Utilizing a Mosby Pain Scale, on post-op day 4, patients experienced Moderate pain, on post-op weeks 1-2, they experienced Mild pain, and on post-op week 3, the average pain score fell between None to Mild. This data shows a positive trend towards no pain by post-op week 3, with the most common score given being 0 on that week. The small increase in pain score on post-op week 4 (1.13) can be explained by the decreased variation in scores with two patients being unavailable at the time the evaluation phone call was performed and one patient having actually stopped using the product by that time.

Also, positive trends were visualized in narcotic use. Overall, only 2 out of 13 patients required a refill of the original 40 pill narcotic prescription, and 1 individual actually didn't even require narcotics during the 6-week post-operative period. There was also a decreasing trend in the weekly use of narcotics. From the day of surgery to post-op week 1, an average of 15 pills were used, from week 1 to week 2, 5 additional pills were used on average, and from week 2 to week 3, on average only 1 additional pill was used. This showed that peak narcotic use took place in the initial 7 days post-op, and reached a plateau around week 2 to week 3, with individuals still having half of their original prescription intact.

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 disclocations, 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.

ADVERSE REACTIONS

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

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.

HOW SUPPLIED

Package Size: 0.33 fl oz (10ml) bottle | 1.01 fl oz (30ml) bottle | 3.04 fl oz (90ml) bottle

Manufactured for:

Gensco Pharma, LLC | Miami, FL 33122 | 855-743-6726 | 855-7GENSCO | www.speedgelrx.com

1 Rheumatology 2006; 45:274–282. Mechanism of the anti-inflammatory effect of colchicine in rheumatic diseases: a possible new outlook through microarray analysis E. Ben-Chetrit, S. Bergmann and R. Sood

2 Widrig, R. Suter,A.: Choosing between NSAID and arnica for topical treatment of hand osteoarthritis in a randomised, double-blind study. Rheumatology International April 2007, Volume 27, Issue 6, pp 585-591

3 European Medicines Agency Assessment Report on Arnica Montana; 9 July 2013 EMA/HMPC/198794/2012 Committee on Herbal Medicinal Products (HMPC)

4 Gál P, Toporcer T, Grendel T, et al: Effect of Atropa belladonna L. on skin wound healing: biomechanical and histological study in rats and in vitro study in keratinocytes, 3T3 fibroblasts, and human umbilical vein endothelial cells. Wound Repair Regen 17: 378-386, 2009

5 P. Gál, T. Vasilenko, et al Atropa Belladonna L. Water Extract: Modulator of Extracellular Matrix Formation in Vitro and in Vivo. Physiol. Res. 61: 241-250, 2012

6 Duran V, Matic M, Jovanovć M, Mimica N, Gajinov Z, Poljacki M, Boza P: Results of the clinical examination of an ointment with marigold (Calendula officinalis) extract in the treatment of venous leg ulcers. Int J Tissue React. 2005;27(3):101-6.

7 Lievre M, Marichy J, Baux S, et al: Controlled study of three ointments for the local management of 2nd and 3rd degree burns. Clin Trials Metaanal 28:9–12, 1992

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