The Innovator
Research Edition
Volume 1

Clinical Studies

Safety and Efficacy of SpeedGel Rx® in the Symptomatic Treatment of Osteoarthritis in the Interphalangeal Joints

Accelerated Resolution of Laser-Induced Bruising with SpeedGel Rx®

Efficacy of Prescription SpeedGel Rx® in Decreasing Post-Operative Surgical Site Pain and Narcotic Use

Got Pain?™
genscolabs.com

Available at Your Local Pharmacy
Ask your Gensco Sales Representative for details.

Pending Clinical Studies

Further clinical trials are underway and more are planned for the near future.

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GENSCO™ LABORATORIES®

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speedgelrx.com

March 2014

SpeedGelRx.com
Indication: Pain, Inflammation and Bruising
Non-Narcotic, Non-Addictive, Non-NSAID
SpeedGel Rx® 10 mL NDC 35781-0210-1
SpeedGel Rx® 30 mL NDC 35781-0210-2

LiDORx.com
Indication: Pain
Non-Narcotic, Non-Addictive, Non-NSAID
LiDORx® 10 mL NDC 35781-0300-1
LiDORx® 30 mL NDC 35781-0300-3

TranzGel.com
Indication: Pain and Inflammation
Non-Narcotic, Non-Addictive, Non-NSAID
TranzGel® 50 mL NDC 35781-0194-5

Patented Isopeutic™ Transdermal Technology | Proprietary MDose™ Metered Technology

SPEEDGEL Rx®

TOPICAL ANTI-INFLAMMATORY/ANALGESIC

SpeedGel Rx® is a next generation prescription homeopathic topical analgesic gel that provides relief of pain and inflammation utilizing a patented Isopeutic™ Transdermal Technology US Patent #5,654,337.

The Gensco patented transdermal drug delivery system used in SpeedGel Rx® carries scientifically formulated active ingredients, proven to relieve pain and inflammation, to the affected site.

- ***Launched January 2012***
- ***Next generation, higher potency***
- ***Available by prescription only***
- ***Odorless, no hot or cold sensation (amber color)***
- ***Non-Narcotic, Non-Addictive, Non-NSAID***
- ***No known drug interactions or adverse side effects***
- ***Gensco's unique metered dose technology (MDose™) dispenses the exact amount of medication (0.25 mL per pump) per application which covers a 2"x2" area of skin***

Next Generation analgesic with greater strength that contains 14 active ingredients (including Zingiber Officinale)

SpeedGel Rx® 10mL **NDC** 35781-0210-1
0.33 fl oz. (10mL) equivalent to **40 doses**
Use 3-4 times over a 24-hour period or as directed by a physician

SpeedGel Rx® 30 mL **NDC** 35781-0210-2
1.01 fl oz. (30 mL) equivalent to **120 doses**
Use 3-4 times over a 24-hour period or as directed by a physician

Ingredients

Active Ingredients	Purpose
Aconitum Napellus 3X	Arthritis, rheumatism, hemostasis, analgesia
Arnica Montana 1X	Stimulates the healing of injured tissues, contusions, reduces edema, bruising and inflammation, analgesic
Belladonna 3X	Localized inflammation, swollen joints
Bellis Perennis 1X	Reduces bruising and edema
Calendula Officinalis 1X	Anti-inflammatory, analgesic, promotes tissue granulation
Chamomilla 1X	Anti-inflammatory, analgesic
Colchicinum Autumnale 3X	**For inflammation and gout**
Echinacea Angustifolia 1X	Reduces inflammation and inhibits hyaluronidase, anti-bacterial
Echinacea Purpurea 1X	Anti-inflammatory, muscle pain
Hamamelis Virginiana 1X	Analgesic, hematomas
Hypericum Perforatum 1X	**Neuropathic pains**
Millefolium 1X	Anti-inflammatory, for bruising and hematomas
Symphytum Officinale 3X	Neuropathy, tendonitus, arthritis
Zingiber Officinale 1X	Anti-inflammatory, analgesic

Inactive Ingredients
Docusate Sodium, Ethyl Alcohol, Isopropyl Myristate, Lecithin, Purified Water, Urea

LiDORx®

MEDICATION FOR PAIN RELIEF

LiDORx® provides topical non-narcotic temporary pain relief.

LiDORx® (Lidocaine HCl USP 3%) applied in controlled doses provides relief of surface pain and utilizes MDose™ Technology which dispenses the exact amount of medication (0.25 mL per pump) per application.

- ***Launched March 2013***
- ***Available by prescription only***
- ***Odorless, colorless gel***
- ***Non-Narcotic and Non-Addictive***
- ***Gensco's unique metered dose technology (MDose™) dispenses the exact amount of medication (0.25 mL per pump) per application which covers a 2"x2" area of skin***

LiDORx® 10mL **NDC** 35781-0300-1
0.33 fl oz. (10mL) equivalent to **40 doses**
Use 3-4 times over a 24-hour period or as directed by a physician

LiDORx® 30 mL **NDC** 35781-0300-3
1.01 fl oz. (30 mL) equivalent to **120 doses**
Use 3-4 times over a 24-hour period or as directed by a physician

Ingredients

Active Ingredients
Lidocaine Hydrochloride 3%

Inactive Ingredients
Deionized Water, Caromer, Isopropyl Alcohol, Petrolatum, Polysorbate-20, Triethanolamine

TRANZGEL®

TRANSDERMAL PAIN RELIEF GEL

TranzGel® is a 1st generation prescription homeopathic topical analgesic gel that provides temporary relief of pain and inflammation utilizing patented Isopeutic™ Transdermal Technology US Patent #5,654,337.

The Gensco patented transdermal drug delivery system used in TranzGel® carries specially formulated active ingredients, proven to relieve pain and inflammation, to the affected site.

- ***Launched 2009***
- ***Available by prescription only***
- ***Odorless, no hot or cold sensation (amber color)***
- ***Non-Narcotic, Non-Addictive, Non-NSAID***
- ***No known drug interactions or adverse side effects***
- ***Gensco's unique metered dose technology (MDose™) dispenses the exact amount of medication (0.25 mL per pump) per application which covers a 2"x2" area of skin***

Contains 13 active ingredients

TranzGel® 50 mL **NDC** 35781-0194-5
1.69 fl oz (50 mL) equivalent to **200 doses**
Use 3-4 times over a 24-hour period or as directed by a physician

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Gensco Laboratories Releases a Research Report on the Safety and Efficacy of 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

Background

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.

Findings:

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.

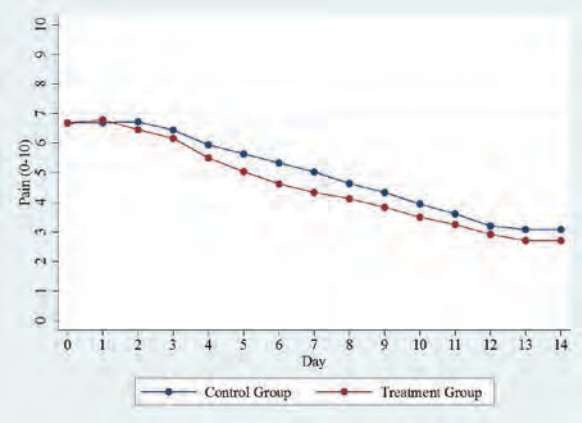

Figure 1. Time Plot of Pain Reduction by Treatment Method

Accelerated Resolution of Laser-Induced Bruising with SpeedGel Rx®

A Rater-Blinded Randomized Controlled Trial

Gensco Laboratories, a leading manufacturer of transdermal medications, demonstrates in a randomized controlled trial that SpeedGel Rx® possesses superior results compared to a placebo in the treatment of bruises with no adverse systemic effects.

Trauma sufficient to cause bruising can occur from a wide variety of situations including accidents, falls, and surgeries. To the extent that bruises can occur on the face or exposed areas, and take days or weeks to resolve, they can be a problematic form of temporary disfigurement. Oral analgesics are commonly prescribed to treat bruising, but these agents often produce adverse systemic effects, which can be severe. Additionally, agents with the coagulative properties required to mitigate bruising may potentially induce undesirable systemic coagulative effects.

SpeedGel Rx® is a prescription homeopathic topically applied transdermal analgesic gel that provides an effective treatment for treating bruises. Non-steroidal topical agents, such as SpeedGel Rx®, offer the potential to provide the same relief provided by oral analgesics but with minimal adverse systemic effects. Gensco Labs designed a randomized, double-blind, placebo-controlled trial to compare the efficacy of SpeedGel Rx® to a placebo in the prevention and resolution of laser induced bruising.

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®.

This research indicates that SpeedGel Rx® is more effective than placebo in reducing the pain and negative appearance associated with bruising. The measurement of specific components of bruising, such as severity and burden of pain are often difficult to combine in a consistent way into the broader aspects of overall quality of life. Given that the goal of medical therapy for bruising focuses on improving aspects of a patient's life, the patient-reported outcomes reported here are important and accepted endpoints in clinical research trials. As such, health care professionals now have SpeedGel Rx® as a viable alternative to oral analgesics in the treatment of bruises.

"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

The prospective project utilizing SpeedGel Rx®, a prescription homeopathic topical analgesic gel, in decreasing post-operative surgical site and overall narcotic use is nearing completion. We are nearing our goal of obtaining 20 patients, who had shoulder or knee procedures (10 each), with an adequate amount of data to utilize for comparison and analysis. Currently we have completed 9 shoulder and 4 knee patients, and are actively in the process of following another 3 shoulder and 4 knee patients.

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.

This project will continue over the next several months, as the final data will be gathered.

Upon completion, a final comparison of the data will be performed and analyzed.

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