

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

Non-NSAID Alternative for Pain, Inflammation and Bruising

SpeedGel Rx® is a prescription transdermal gel that provides relief of pain, inflammation and bruising, utilizing patented Isopeutic™ Transdermal Technology, US Patent #56545337. 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 specifically applied directly to the affected site, minimizing side effects, interactions and comorbidities caused by oral therapies and topical NSAIDs. Furthermore, SpeedGel Rx® is clinically proven to reduce narcotic use.

All Gensco products, including SpeedGel Rx®, are distributed to pharmacy chains such as Walgreens®, CVS®, Walmart®, RiteAid®, Kroger® and Publix® through the major wholesalers such as McKesson, Cardinal and AmerisourceBergen. SpeedGel Rx® is contracted with DAPA (Contract #SP0200-15-H-0003), Federal Supply Schedule (FSS), making it accessible to all military personnel and is also available to all MEDICARE patients (Medicare Contract #P1466).

Indications

- Inflammatory conditions of joints and soft tissues of the hand, wrist, elbow, shoulder, neck, back, knee, ankle and toe
- Injuries such as sprains, strains and dislocations
- Arthritis
- · Repetitive/overuse injuries
- · Post-surgical edema
- · General aches and pains
- · Contusions and trauma



SpeedGel Rx® Product Overview

Product Overview

SpeedGel Rx® is a proprietary combination of active ingredients, four of which are prescription, manufactured with a patented transdermal delivery system. Among the prescription ingredients is: 1) Colchicinum Autumnale, also known as Colchicine, which is a well-known, strong and effective anti-inflammatory medication; 2) Belladonna, an anti-inflammatory medication for localized inflammation and swollen joints; 3) Arnica Montana, which stimulates the healing of injured tissues and contusions, reduces edema, bruising and inflammation, and acts as an analgesic; and 4) Hypericum Perforatum, commonly used for its neurological analgesic effects.

Indications

Indicated for the relief of pain, inflammation and bruising from:

- Inflammatory conditions of joints and soft tissues of the hand, wrist, elbow, shoulder, neck, back, knee, ankle and toe
- · Injuries such as sprains, strains and dislocations
- Arthritis
- Repetitive/overuse injuries
- · Post-surgical edema
- · General aches and pains
- · Contusions and trauma

Inflammation

SpeedGel Rx® contains several ingredients that produce anti-inflammatory effects. Most notably, Colchicinum Autumnale (Colchicine), 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 Colchicinum Autumnale (Colchicine) 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. Colchicinum Autumnale (Colchicine), as formulated in SpeedGel Rx®, does not share the adverse drug effects associated with the oral (systemic) preparations of colchicine.

SpeedGel Rx® demonstrates anti-inflammatory effects commonly seen with the Non-Steroidal Anti-Inflammatory (NSAID) class of drugs and therefore, should be considered an alternative to this class. NSAIDs are, by far, the most commonly utilized medication class for the relief of mild to moderate musculoskeletal pain. Though these medications are highly effective, they do have many adverse effects and are often not the best choice for many patients.

There are many side effects, interactions and comorbidities associated with the use of NSAIDs. These include but are not limited to allergic reactions, bleeding, kidney failure and rarely liver failure. According to several studies, NSAIDs cause an increased risk of serious, even fatal, stomach and intestinal

adverse reactions such bleeding, ulcers and perforation of the stomach and intestines. These events can occur at any time during treatment and without warning symptoms. Due to NSAIDs' effects on clotting time, it is necessary to stop their use two weeks prior to surgery. In addition, the risk of myocardial infarctions and cerebral vascular hemorrhage in patients with a history of cardiovascular disease prompted the FDA to require a Black Box warning on NSAID products.

Musculoskeletal Pain

There is extensive consensus that overuse of prescription pain medication in the US has reached epidemic levels. An analysis by the California Worker's Compensation Institute identified prescription opioid medications as the largest single class of drug dispensed in 2014, accounting for nearly 27.2% of all workman's compensation related prescriptions and 24.7% of current drug spend. The analysis concludes that clinicians must consider alternative therapies that will limit or decrease the utilization of opioids.²

SpeedGel Rx® is effective in the management of pain associated with musculoskeletal injuries by reducing inflammation and improving wound healing. SpeedGel Rx®, which is non-narcotic and has no neurocognitive effects, allows patients to return to normal activities of daily living including operating equipment and machinery and returning to work. By decreasing inflammation and associated pain, SpeedGel Rx® allows patients to reduce the use of more high-risk medications, such as opiates.

An ongoing evaluation of SpeedGel Rx® by Dr. James Andrews and his research institute (AMRI), has demonstrated the benefits of this medication. SpeedGel Rx® was utilized postoperatively on patients requiring ACL reconstruction surgery, measuring patient's perception of pain and evaluating the use of opiates for pain control. Results show a 19% reduction of pain at Day 7 and 26% Day 21. Improvement in Range of Motion in comparison to placebo results are 12.8% at Day 14 and 7.2% Day 28. As a result of the patients' experience, there is a faster pain resolution with SpeedGel Rx® while they correspondingly have less need of narcotics.

Since SpeedGel Rx® does not contain any counterirritants such as menthol or capsaicin there is no potential for related skin injury including chemical burns, which prompted a FDA warning on the use of products containing counterirritants.³

Bruising

SpeedGel Rx®, containing prescription Arnica Montana, Atropa Belladona and Calendula Officialis, has been shown to have positive effect on wound healing, pain associated with bruising and time for bruise resolution.⁴

A recent study was conducted evaluating the effects of SpeedGel Rx® in the resolution of laser-induced bruising. The results demonstrate that SpeedGel Rx® reduced pain more quickly than placebo and 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®.

Summary of Product Research

SpeedGel Rx® is effective in the management of pain associated with musculoskeletal injuries by reducing inflammation and improving wound healing. SpeedGel Rx®, which is non-narcotic and has no neurocognitive effects, allows patients to return to normal activities of daily living including operating equipment and machinery and returning to work. By decreasing inflammation and associated pain, SpeedGel Rx® allows patients to reduce the use of more high-risk medications, such as opiates.

SpeedGel Rx® has been evaluated in treatment of osteoarthritis, bruising and postoperative pain.

In the study that evaluated the efficacy of SpeedGel Rx® for the treatment of Osteoarthritis of the Interphalangeal joints, the results demonstrated an overall 60% reduction in pain for the treatment group from baseline.⁵

The bruising study demonstrated that SpeedGel Rx® was more effective than placebo in reducing the pain and negative appearance associated with laser-induced bruising. Subjects reported a 15% reduction in pain and a 10% increase in healing time compared with placebo.⁴

In an ongoing evaluation of SpeedGel Rx® by Dr. James Andrews and his research institute (AMRI), there was overwhelming evidence of the benefits of this medication. SpeedGel Rx® was utilized postoperatively on patients requiring ACL reconstruction surgery, measuring patient's perception of pain, Range of Motion and evaluating the use of opiates for pain control. The results showed that patients experienced faster (19% reduction at Day 7 and 26% at Day 21) pain resolution with SpeedGel Rx® while requiring significantly less need and usage of postoperative narcotics. There also was a 12.8% increase in Range of Motion at Day 14 and 7.2% increase at Day 28).

The study participants did not report any rash or skin irritation effects and no patients were discontinued due to adverse effect. SpeedGel Rx® does not contain any counterirritants such as menthol or capsaicin there is no potential for related skin injury including chemical burns.

SpeedGel Rx® Regulatory Overview and Prescription Status

SpeedGel Rx® is a drug under FDA regulation and HPUS monograph. Moreover, 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. Attached are the HPUS Monographs for the Prescription ingredients of SpeedGel Rx®.

In the case of SpeedGel Rx®, four of the active ingredients utilized are prescription. These are: 1) colchicinum autumnale, 2) belladonna, 3) arnica montana, and 4) hypericum perforatum. Attached are copies of the monographs for each of these active ingredients. Colchicinum autumnale is utilized for its anti-inflammatory results, which is why it is also used for gout.

Homeopathic Regulatory Review

SpeedGel Rx® is a prescription drug that falls under the FDA's definition of a Homeopathic drug. Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act (Act) defines the term

"drug" to mean articles recognized in the official United States Pharmacopeia (USP), the official Homeopathic Pharmacopeia of the United States (HPUS), or official National Formulary (NF) or any supplement to them.

The FDA has granted the Homeopathic Pharmacopeia Convention of the United States (HPCUS) with the authority to compile and revise the HPUS. The HPCUS is a non-governmental, non-profit scientific organization composed of experts in the fields of medicine, arts, biology, botany, chemistry and pharmacy who have the appropriate training and experience and have demonstrated additional knowledge and interest in the principles of homeopathy. The HPCUS is an autonomous body, which works closely with the FDA and homeopathic organizations that designate safe and efficacious ingredients to be used in homeopathic medicines.

The HPCUS ensures and approves ingredients for listing within the HPUS. Such approval requires that the ingredients be safe and effective with sufficient clinical data. The process for review is formal, as are the criteria for acceptance. All activities of the HPCUS are published for 90 days for public comment, similar to FDA-proposed regulations.

Product Summary

The synergy of the ingredients contained in SpeedGel Rx®, in combination with a patented transdermal delivery system, produce a superior transdermal prescription medication for the treatment of musculoskeletal injuries including sprain, strains, and contusions. SpeedGel Rx® has proven efficacy in decreasing inflammation, reducing associated pain, and bruise resolution. This product should be considered a first-line treatment and standard of care option, either alone or in conjunction with other treatment modalities for soft tissue injuries. Additionally, the proven ability of SpeedGel Rx® to curb and curtail the need for opiate use in the management of pain associated with soft tissue injuries is an important consideration for the clinician concerned with opiate addiction and abuse as well improving the patient experience.

References

- 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 https://www.cwci.org/research.html
- B FDA Drug Safety Communication: Rare cases of serious burns with the use of over-the-counter topical muscle and joint pain relievers; http://www.fda.gov/drugs/drugsafety/ucm318858.htm
- 4 Accelerated Resolution of Laser-Induced Bruising with SpeedGel Rx®: A Rater-Blinded Randomized Controlled Trial
- 5 A Randomized, Double-Blind, Clinical Study to Evaluate the Safety and Efficacy of SpeedGel Rx® in the Symptomatic Treatment of Osteoarthritis in the Interphalangea Joints
- 6 "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
- 7 http://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074360.htm



..Indications

analgesia

Inflammation locally

Analgesia, inflammation

.Inflammation and gout

.Neuropathic pains .Hematomas, wound healing

..Inflammation

.Neuralgia, rheumatism, hemostasis, analgesia

Stimulates healing of injured tissues, wounds,

contusions, hematomas, neuralgia, myalgia,

.Dislocations, bruising, reducing edema

.Stimulates fibroblasts, inflammation

Astringent, analgesic, hematomas

.Inflammation, promotes healing of tissues

Neuropathy, causalgia, contusions, periostitis

Common Name

Mountain arnica

. Deadly nightshade.

Echinacea Angustifolia Narrow leaf cone flower...Inflammation and inhibits hyaluronidase

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

.. Monk's-hood.

. Daisy .

.. Yarrow ..

. Chamomile.. Colchicine



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.

 $SpeedGel\ Rx^{\emptyset}\ is\ an\ amber\ colored,\ odorless\ gel\ dispensed\ in\ a\ patented\ metered\ dose\ container\ (MDose)\ containing\ either\ 10ml,\ 30ml,\ or\ 90ml.$

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 ngs (Gensco® Pharma Tube vs. Pump Study)

Ingredients ..

Belladonna....

Bellis Perennis.

Chamomilla.....

Colchicinum

Millefolium..

Arnica Montana..

Aconitum Napellus

Calendula Officinalis...... Calendula .

Hamamelis Virginiana Witch-hazel..

Symphytum Officinale..... Comfrey.

Zingiber Officinale...... Ginger.

Hypericum Perforatum., St. John's wort....

Echinacea Purpurea...... Purple cone flower...

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^{θ} 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 inflammation² and bruising³. 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. 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.
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. 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. 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:

- By day two pain was lower in the treatment group than the control group.
- By day five pain was over 10% lower in the treatment group
- Overall a 60% reduction in pain was found between the treatment group from baseline.
- No subject in the treatment group reported a side effect.
- 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 on the same of the post-op week 3. The average pain scores 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 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®.

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 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. Safe to use on children over 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 Laboratories, LLC | Miami, FL 33122 | 866-608-6284 | 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. Gǎl, 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