

## ***SINECCH™ FROM ALPINE PHARMACEUTICALS – THE ARNICA EXPERTS!*** **CLINICAL TRIAL DATA & JOURNAL REFERENCES** **FOR POST-SURGICAL RECOVERY**

SINECCH™ is Alpine Pharmaceutical's clinically proven, oral OTC, high dosage regimen of homeopathic Arnica montana specifically developed by a pharmacist, who was a homeopathic pharmacist, to reduce bruising and swelling following surgery. It is SINECCH's unique programmed dosing regimen alone, of all Arnica regimens, that has been demonstrated to be statistically significant in promoting post-op recovery in four clinical research studies including its safety and efficacy in a Post Marketing Surveillance Report; these SINECCH studies are the studies frequently cited to show the efficacy of homeopathic Arnica for post-surgical recovery.<sup>1,2,3,4,5,6</sup> SINECCH has these statistically significant results as our dosing regimen provides the correct dose at the correct time for post-surgical recovery.<sup>8</sup> One SINECCH study is a University of California, San Francisco Medical Center clinical study which shows that patients taking the SINECCH regimen recover in as little as half the time of patients taking placebo after major surgery.<sup>2</sup> SINECCH is proven to be safe and effective, to speed post-op recovery and get patients back to their regular routine.

Since 1997, Alpine Pharmaceuticals has distributed over 1,250,000 SINECCH dose packs of homeopathic Arnica to plastic surgeons, dermatologists, oral surgeons, and patients. SINECCH is the only homeopathic Arnica montana dosing regimen to be proven in four plastic surgery clinical trials to reduce post-op bruising and swelling.<sup>1,2,3,4,5,6</sup> Over the past several years, Alpine Pharmaceuticals' dosing regimen has become increasingly popular with medical professionals and professional medical journals have taken notice. Articles from the American Medical Association endorsed journal, Archives of Facial Plastic Surgery, and Plastic and Reconstructive Surgery, a journal of the American Society of Plastic Surgeons, The American Journal of Therapeutics, and Annals of Plastic Surgery reference the wide usage, effectiveness, and safety of SINECCH:

- "Arnica Safety and Efficacy Report," Plastic and Reconstructive Surgery, Vol. 112 No.4, September 2003, p. 1164-66. The article states that "Arnica montana, marketed as SINECCH by Alpine Pharmaceuticals (San Rafael, California), is used by many plastic surgeons to limit postoperative edema and ecchymosis." In this article, the DATA Committee (Device And Technology Assessment expert panel of the American Society of Plastic Surgeons) reviewed all the Arnica research that they found to be scientifically well conducted. Unfortunately, in the description of the studies, they did not differentiate between low dose (30C, 30X strength and lower) homeopathic Arnica and high dose (200C, 1M (1000C) strength and higher) homeopathic Arnica. Of the 10 studies reviewed, none of the low dose Arnica studies demonstrated statistically significant differences between the Arnica groups and the placebo groups. **Only 2 out of the 10 studies demonstrated statistically significant differences between the Arnica groups and the placebo groups. These were the 2 studies using SINECCH's specifically designed high dosage Arnica regimen for surgical recovery. The SINECCH studies were in facelift and liposuction, two major cosmetic surgeries.** Statistical P values for these 2 SINECCH studies were in the thousandths and ten thousandths place respectively.<sup>1,2,4,6</sup>
- The SINECCH facelift study conducted at the University of California, San Francisco, was published in "Effects of Homeopathic Arnica montana on Bruising in Face-lifts, Results of a Randomized, Double-blind, Placebo-Controlled Clinical Trial," Dr. Seeley, Dr. Denton, Dr. Ahn, Dr. Maas, Archives of Facial Plastic Surgery, Vol. 8, January/February 2006, p. 54-59. Taking the SINECCH and placebo data presented in this study, graphing it on a post-operative day 1 through 10 scale and comparing the area under the curve, **the placebo group had 25% more bruising and 50% longer recovery time than the SINECCH group.**<sup>2</sup>
- **A comparison of the effectiveness of SINECCH to steroids** in a rhinoplasty study is found in, "A Randomized, Controlled Comparison between Arnica and Steroids in the Management of Postrhinoplasty Ecchymosis and Edema," Dr. Totonchi, Dr. Guyuron, Plastic and Reconstructive Surgery, Vol. 120, No. 1, July 2007, p. 271-274. **"We conclude from this study that both**

**arnica and corticosteroids are efficacious in significantly reducing post-rhinoplasty edema within 2 days after surgery**, with its resolution within 8 days. However, the trend ( $p = 0.06$ ) for increased ecchymosis on day 2 and a delay in its resolution after administration of corticosteroids renders the benefits of corticosteroids questionable.”<sup>3</sup> The **SINECCH group had less bruising than either the Control group or the steroid group. SINECCH significantly and effectively reduces swelling after rhinoplasty as well as steroids, but without the side effects of steroids.**<sup>3,5</sup>

- **A Post Marketing Surveillance Report on the safety and efficacy of SINECCH** was conducted by WooilPharm, over the period of three years beginning in 2010 in order for SINECCH to achieve permanent approval as a prescription drug in South Korea. PMS was conducted at 19 hospitals with 650 study patients. During PMS, **NO adverse side effects** were reported. According to the PMS self-evaluation survey, **100% of patients reported SINECCH was effective** in reduction of post-op bruising and swelling.<sup>5</sup> Additionally, **since its debut in 1997 with more than 1,000,000 dose packs distributed, there are no reported SinEcch cases on the US FDA Adverse Event Reporting System (FAERS).**<sup>7</sup>

Homeopathic dosage regimens are significantly different from the regimens of either conventional medications or herbs and dietary supplements. Dr. David Riley provides an excellent introduction to homeopathic dosing in “Arnica Montana and Homeopathic Dosing Guidelines,” Dr. David Riley, Plastic and Reconstructive Surgery, Vol. 112, No. 2, August 2003, p. 693. Dr. Riley is a MD, board-certified in internal medicine, and a technical consultant to the FDA for regulatory issues related to homeopathy. The author discusses the appropriate dose and dosing regimen of Arnica for plastic surgery or major trauma. **Dr. Riley recommends a high dose of homeopathic Arnica montana in the strengths of 200C, 1M (1,000C) or 10M (10,000C) “for major surgical procedures** involving extensive bruising and swelling. . . .”<sup>8</sup> SINECCH uses three initial doses of the 1M (1000C) strength of homeopathic Arnica montana, in accordance with Dr. Riley’s dosing guidelines.

When you recommend SINECCH with its unique dosing regimen to your patients, you will have the confidence that they will receive an optimal dose of Arnica, ensuring a superior outcome while avoiding potential problems.<sup>8</sup> One such **problem can be too many pre-procedure doses of oral Arnica**, regardless of the strength of the medication, **can lead to paradoxical increase in intra-operative bleeding** in a small percentage of patients.<sup>8</sup> SINECCH uses only one pre-procedure dose of Arnica. Since 1997, there has never been a reported case of increased intra-operative bleeding when following the SINECCH dosing regimen. Just as with conventional medications, the dosage strength and regimen of a homeopathic medication may determine whether the drug is beneficial, useless, or detrimental to the patient. Taking the correct dose of homeopathic medications is critical to achieve the desired results. **The evidence of four plastic surgery clinical trials clearly shows that the SINECCH regimen has proven to be more effective than other dosing regimens when it comes to healing from major surgery.**<sup>1,2,3,4,5,6</sup> Together with your surgical expertise, using SINECCH will provide your patients with a faster post-surgical recovery!

1. “Arnica Safety and Efficacy Report,” Plastic and Reconstructive Surgery, Dr. Lawrence and DATA Committee, Vol. 112 No.4, September 2003, p. 1164-66.

2. “Effects of Homeopathic Arnica montana on Bruising in Face-lifts, Results of a Randomized, Double-blind, Placebo-Controlled Clinical Trial,” Dr. Seeley, Dr. Denton, Dr. Ahn, Dr. Maas, Archives of Facial Plastic Surgery, Vol. 8, January/February 2006, p. 54-59.

3. “A Randomized, Controlled Comparison between Arnica and Steroids in the Management of Postrhinoplasty Ecchymosis and Edema,” Dr. Totonchi, Dr. Guyuron, Plastic and Reconstructive Surgery, Vol. 120, No. 1, July 2007, p. 271-274.

4. “Arnica Montana in the Reduction of Ecchymosis and Edema in Liposuction,” Dr. Kulick, Presented at the American Society of Aesthetic Plastic Surgery, Las Vegas, April 2002.

5. SINECCH Capsule Post Marketing Surveillance Report, Wooilpharm Co., Ltd., December 2012

6. “Effectiveness and Safety of Arnica Montana in Post-Surgical Setting, Pain and Inflammation,” Tommaso Iannitti, PhD,<sup>1</sup>\* Julio Cesar Morales-Medina, PhD,<sup>2</sup> Paolo Bellavite, MD,<sup>3</sup> Valentina Rottigni, MSC,<sup>4</sup> and Beniamino Palmieri, MD, PhD<sup>4</sup>, The American Journal of Therapeutics, September 2014

7. US FDA MedWatch Voluntary Report  
[http://google2.fda.gov/search?q=SinEcch&x=0&y=0&filter=0&proxystylesheet=FDAgov&output=xml\\_no\\_dtd&sort=date%253AD%253AL%253Ad1&site=FDAgov-MedWatch-Safety&requiredfields=-archive%](http://google2.fda.gov/search?q=SinEcch&x=0&y=0&filter=0&proxystylesheet=FDAgov&output=xml_no_dtd&sort=date%253AD%253AL%253Ad1&site=FDAgov-MedWatch-Safety&requiredfields=-archive%253A)

8. “Arnica montana and Homeopathic Dosing Guidelines,” Dr. David Riley, Plastic and Reconstructive Surgery, Vol. 112, No. 2, August 2003, p. 693.

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