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# COMPOUNDING PHARMACY SOLUTIONS

PRESCRIPTION COMPOUNDING



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## PRESCRIPTION COMPOUNDING FOR

# PAIN MANAGEMENT

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## OSTEOARTHRITIS PAIN

The results of the following review find that topical diclofenac may be useful in treating osteoarthritis pain -“Safety and efficacy of topical diclofenac sodium gel for knee osteoarthritis in elderly and younger patients: pooled data from three randomized, double-blind, parallel-group, placebo-controlled, multicentre trials” (Drugs Aging. 2011 Jan 1;28(1):27-40).

**BACKGROUND:** NSAIDs used for the treatment of osteoarthritis (OA) have dose-related risks for gastrointestinal, cardiovascular and renal adverse events (AEs), particularly in elderly patients. Topical NSAIDs reduce systemic NSAID exposure and may mitigate these risks.

**OBJECTIVE:** To evaluate the safety and efficacy of topical diclofenac sodium 1% gel (DSG) versus vehicle in patients aged 25-64 or ≥65 years who have been diagnosed with knee OA.

**STUDY DESIGN:** Pooled data from three 12-week, randomized, double-blind, parallel-group, multicentre trials.

**SETTING:** US primary care, internal medicine, orthopaedic and rheumatology practices.

**PATIENTS:** Aged ≥25 years with mild to moderate (Kellgren-Lawrence grade 1-3) knee OA.

**INTERVENTION:** After a 1-week analgesic washout, patients applied 4 g of DSG or vehicle four times daily to one knee. Rescue paracetamol (acetaminophen) up to 4 g/day was allowed.

**MAIN OUTCOME MEASURE:** Key efficacy outcomes common to the three trials were Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain (0-20) and physical function (0-68) subscales, global rating of disease (GRD; 100-mm visual analogue scale [VAS]) and pain on movement (POM; 100-mm VAS). ANOVA was used to compare efficacy outcome differences (DSG vs vehicle) by age (25-64 or ≥65 years). A flare design was used that defined a subset of patients who experienced increased pain during the washout period (modified efficacy subpopulation [MES]).

**RESULTS:** The MES included both patients aged 25-64 (n = 602) and ≥65 (n = 374) years. Patients in each age group applied >90% of scheduled doses. Among patients aged 25-64 years, the improvement from baseline to week 12 (least squares mean [standard error]) was greater for DSG versus vehicle for WOMAC pain (-5.8 [0.3] vs -4.7 [0.3], p = 0.007), WOMAC physical function (-17.9 [0.9] vs -14.2 [0.9], p = 0.002), GRD (-29.5 [1.6] vs -23.8 [1.6], p = 0.01) and POM (-37.3 [1.8] vs -29.0 [1.8], p < 0.001). Among patients aged ≥65 years, the improvements from baseline for most efficacy outcome scores were significantly greater with DSG versus vehicle: WOMAC pain (-5.3 [0.3] vs -4.1 [0.4], p = 0.02), WOMAC physical function (-15.5 [1.1] vs -11.0 [1.1], p = 0.004) and POM (-33.7 [2.2] vs -26.4 [2.2], p = 0.02). The efficacy of DSG did not differ significantly between patients aged 25-64 years and ≥65 years: WOMAC pain (p = 0.85), WOMAC physical function (p = 0.70), GRD (p = 0.86) and POM (p = 0.81). The incidence of any AE was greater with DSG than with vehicle among patients aged 25-64 years (56.6% vs 50.8%) and ≥65 years (55.8% vs 43.9%). Treatment-related application site dermatitis was more common with DSG compared with vehicle in both younger (4.0% vs 0.7%, respectively) and older (5.8% vs 0.4%, respectively) patients and was the main reason for the difference in treatment-related AEs between the DSG and vehicle groups. Gastrointestinal AEs were infrequent among patients treated with DSG and similar to incidence rates with vehicle in both age groups.

**CONCLUSIONS:** DSG was effective and generally well tolerated in adults regardless of age. These data support the topical application of DSG for relief of OA knee pain in elderly and younger patients. PMID:21174485

An example of how you might prescribe follows:

We can compound diclofenac into a topical gel.

### COMPOUNDED MEDICATION

**Diclofenac 2.5%**

**Topical Gel**

**120gm**

**Apply to affected areas sparingly TID**

**CHRONIC PAIN**

The following clinical paper reviews medications that have proven effective in chronic pain disorders and how their use in combination should improve the management of chronic pain -“Pharmacotherapy of chronic pain: a synthesis of recommendations from systematic reviews” (Gen Hosp Psychiatry. 2009 May-Jun;31(3):206-19).

**OBJECTIVES:** Chronic pain is one of the most prevalent, costly and disabling conditions in both clinical practice and the workplace, yet often remains inadequately treated. Moreover, chronic pain commonly co-occurs with depression, anxiety and somatoform disorders, and adversely affects response of these conditions to psychiatric treatments. This article provides an evidence-based approach to the pharmacotherapy of chronic pain.

**METHODS:** This narrative review is derived largely from meta-analyses and systematic reviews published since 2005. For a few medications, findings from multiple recent trials are synthesized if a systematic review had not yet been published. Classes of medications are first reviewed, followed by an overview of four common pain disorders: neuropathic pain, low back pain, fibromyalgia and osteoarthritis.

**RESULTS:** A stepped care approach based upon existing evidence includes (1) simple analgesics (acetaminophen or nonsteroidal anti-inflammatory drugs); (2) tricyclic antidepressants (if neuropathic, back or fibromyalgia pain) or tramadol; (3) gabapentin, duloxetine or pregabalin if neuropathic pain; (4) cyclobenzaprine, pregabalin, duloxetine, or milnacipran for fibromyalgia; (5) topical analgesics (capsaicin, lidocaine, salicylates) if localized neuropathic or arthritic pain; and (6) opioids. Disease-specific recommendations for neuropathic, low back, fibromyalgia and osteoarthritis pain are reviewed.

**CONCLUSION:** A number of medications have proven effective in chronic pain disorders and their use individually or in combination should improve the management of chronic pain. PMID: 19410099

With our state of the art compounding lab and pharmaceutical knowledge and experience, we can compound several of the above medications into one transdermal cream. These combinations in a transdermal delivery form may help to increase compliance and reduce patient medication costs.

An example of how you might prescribe follows:

COMPOUNDED MEDICATION
<p><b>Ketoprofen 10% / Amitriptyline 2% / Gabapentin 1%</b>  <b>Transdermal Cream</b>                      90gm                      Apply sparingly to affected area(s) TID</p>

## LOW BACK PAIN

The results of this study demonstrated that patients with muscle spasm associated with acute low back strain benefited from the use of combination therapy consisting of a nonsteroidal anti-inflammatory agent (naproxen) and a muscle relaxant (cyclobenzaprine) - "Cyclobenzaprine and naproxen versus naproxen alone in the treatment of acute low back pain and muscle spasm" ([Clin Ther.](#) 1990 Mar-Apr;12(2):125-31).

**ABSTRACT:** "Two groups of 20 patients each, with mild to moderate acute low back pain with associated muscle spasm of ten days' duration or less, were treated with a combination of cyclobenzaprine and naproxen or naproxen alone in a randomized, 14-day open-label trial. Cyclobenzaprine was added to the naproxen regimen as an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful, musculoskeletal conditions. The clinical characteristics of each study group, including the number of worker's compensation patients, were comparable. Combination therapy was associated with less objective muscle spasm and tenderness and greater motion of the

lumbosacral spine (P less than 0.05). There were trends toward faster resolution of functional deficits and pain with combined therapy. Combination therapy was associated with more side effects, due primarily to drowsiness from the cyclobenzaprine. The results of this study demonstrated that patients with muscle spasm associated with acute low back strain benefited from the use of combination therapy consisting of a nonsteroidal anti-inflammatory agent (naproxen) and a muscle relaxant (cyclobenzaprine)." PMID: 2141299

With our state of the art compounding lab and pharmaceutical knowledge and experience, we can compound naproxen and cyclobenzaprine into one transdermal gel. This form of delivery may help to minimize the systemic side effects associated with oral dosing.

An example of how you might prescribe follows:

### COMPOUNDED MEDICATION

**Naproxen 10% / Cyclobenzaprine 0.5%**

**Transdermal Gel**

90gm

Apply sparingly to affected area BID-TID PRN

Prescriber Name \_\_\_\_\_

Prescriber Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

Phone \_\_\_\_\_ Fax \_\_\_\_\_

Date \_\_\_\_\_ Patient Name \_\_\_\_\_ DOB \_\_\_\_\_

Address \_\_\_\_\_ City/State/Zip \_\_\_\_\_ Phone \_\_\_\_\_

Patient will pick up at pharmacy       Please ship to patient

*All topical compound %s are per 1 ml or 1 gm unless otherwise noted*

**Osteoarthritis Pain**

[ ] Diclofenac 2.5%      Topical Gel

Quantity 120gm      Directions: Apply to affected areas sparingly TID

**Chronic Pain**

[ ] Ketoprofen 10% / Amitriptyline 2% / Gabapentin 1%      Transdermal Cream

Quantity 90gm      Directions: Apply sparingly to affected area(s) TID

**Low Back Pain**

[ ] Naproxen 10% / Cyclobenzaprine 0.5%      Transdermal Gel

Quantity 90gm      Directions: Apply sparingly to affected area BID-TID PRN

**Directions**

\_\_\_\_\_  
\_\_\_\_\_

Prescriber's Signature \_\_\_\_\_ Refills: 1 2 3 4 5 6 7 8 9 10 11 12 NR

# Compounding Pharmacy Solutions



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