MEDCO FORUM®

PRESENTING INNOVATIVE PRODUCTS & SERVICES TO HEALTHCARE PROFESSIONALS

VOLUME 12 NUMBER 37 SEPTEMBER 2005

REPRINT

FLEXERIL® (CYCLOBENZAPRINE HCL) 5 MG T.I.D. IS AS EFFECTIVE AS CYCLOBENZAPRINE 10 MG T.I.D. IN RELIEVING BACK PAIN ASSOCIATED WITH MUSCLE SPASM

Musculoskeletal pain, particularly back pain, is a huge medical and economic problem in the United States. In 1998, the health care expenditures for individuals with back pain were reported to be $90.7 billion (*1*). It is estimated that at any given time, 15% to 20% of the people in the United States have back pain (*2*). Low back pain is one of the most common reasons why patients go to a family physician.

Most commonly, back pain is due to muscle strains and stresses. Most experts agree that a brief period of rest followed by return to activity is the best method of treatment. Prolonged bed rest is not advised, because muscles become weaker. In fact, research has shown clearly that individuals with low back pain should remain active (following a brief period of rest) in the weeks after an acute episode (*3*, *4*). Treating back pain effectively is necessary in order to allow the patient to remain active. This, in turn, may allow the patient to return to his or her normal work, leisure, and sporting activities sooner.

Painful Conditions in the Work-Place Are Costly

The lifetime prevalence of low back pain has been reported to range from 60% to 80% and is associated with substantial socioeconomic impact (*5*). In fact, in 1999, back or spine problems were the second leading cause of disability in adults in the United States, accounting for 16.5% (6.8 million) of all disability cases reported that year (*6*). In 1990, direct medical costs from back pain in the United States including hospitalizations, outpatient services, physician visits, medications, and nursing home costs totaled more than $24 billion. Indirect costs, which include disability compensation and lost work productivity, being more difficult to calculate, may be estimated to be >300% to 400% higher than direct medical costs and, therefore, may account for another $75 billion (*5*). Indeed, in a recent survey of working adults in the United States, respondents with back pain experienced a mean loss of productive time (not absence) of 5.28 hours per week at an estimated total cost of $19.8 billion (*7*). This number excludes the cost of disability compensation.

Flexeril 5 mg Is As Effective As The 10-mg Tablet

Flexeril 5 mg is a lower-dose version of the most trusted and prescribed muscle relaxant, Flexeril 10 mg. The active ingredient in Flexeril is cyclobenzaprine. Flexeril 5 mg relieves painful muscle spasm when used along with rest and physical therapy for up to 2 to 3 weeks. The U.S. Food and Drug Administration approved Flexeril 5 mg in February 2003. Previously, the drug had only been available as a 10-mg tablet.

According to Peter P. Toth, MD, PhD, a family physician at the Sterling Rock Falls Clinic, Sterling, IL, "The 5-mg tablet given t.i.d. is associated with less sedation and adverse side effects, it accelerates recovery rates by 2 days as compared to placebo, and substantially reduces pain and muscle spasm as well as the 10-mg tablet taken t.i.d. Of all skeletal muscle relaxation agents, Flexeril 5 mg has the best placebo-controlled trials in a population of patients with back pain than any other comparator skeletal muscle relaxation agent. Flexeril 5 mg has the most convincing data and is highly efficacious," Dr. Toth added.

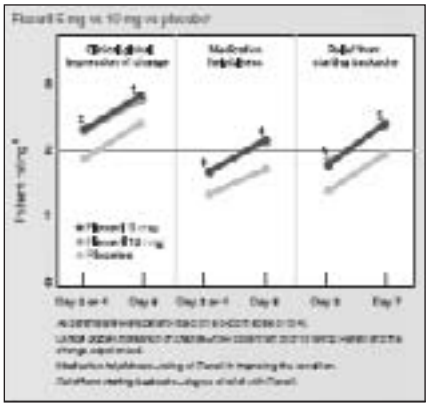
Primary Care Studies Show Flexeril 5 mg Is Effective for Acute Musculoskeletal Spasm

Researchers conducted two randomized, double-blind, placebo-controlled, parallel-group trials at primary care centers in the United States (*8*). In one study, 737 patients with acute, painful muscle spasm were randomized to receive either 5 mg or 10 mg cyclobenzaprine t.i.d. or placebo for 7 days. The other study involved 668 patients who received either 2.5 mg or 5 mg cyclobenzaprine or placebo for 7 days. The studies were designed to assess the efficacy and tolerability of cyclobenzaprine compared with placebo.

The researchers found that on days 3 and 7, significantly more patients in the 5-mg or 10-mg cyclobenzaprine groups reported pain relief compared with placebo ($p < 0.05$). Pain relief was reported within 3 or 4 doses of the 5-mg tablet. Importantly, the 5-mg dose was equally as effective as the 10-mg dose, and was associated with a significantly lower incidence of sedation (*8*). However, the researchers concluded that the 2.5-mg dose was not significantly more effective than the placebo.

David G. Borenstein, MD, Clinical Professor of Medicine at George Washington University Medical Center, who coauthored the report, said, "The study shows that a lower dose of medicine than had been originally investigated was quite effective and had less side effects—less sedation, less dryness of the mouth—and patients get the similar benefit. Sometimes less is better. It always has been thought that muscle relaxants work by making people sleepy so they can go to bed. With the effective 5-mg t.i.d. dose, 69% of the people got the benefit without any sedation at all. In addition, people who took Flexeril 5 mg t.i.d. got better 30% faster than those who did not, that is, two days earlier," Dr. Borenstein added.

Flexeril 5 mg Is As Effective As Flexeril 10 mg in All three Primary Efficacy Parameters.



Conclusion

Clinical research shows that Flexeril 5 mg t.i.d. is as effective as cyclobenzaprine 10 mg t.i.d. in relieving muscle spasm associated with back pain and painful musculoskeletal conditions. Flexeril 5 mg also produces significantly less drowsiness than the 10-mg dose, which is important in allowing productive function along with the pain relief produced after 3 or 4 doses. Since research has shown that early activity is important to speed recovery, Flexeril 5 mg t.i.d. is an effective solution for patients with acute back pain.

Flexeril 5 mg is indicated only as an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions and should only be used for short periods (up to 2 to 3 weeks).

Flexeril should not be taken by patients during acute recovery phase of myocardial infarction (MI) or by patients with arrhythmias, heart block, conduction disturbances, congestive heart failure, allergies to cyclo-benzaprine or other ingredients in Flexeril, hyperthyroidism, current/recent use of monoamine oxidase inhibitors (MAOIs). Hyperpyretic crisis seizures and deaths have occurred in patients receiving cyclobenzaprine concomitantly with MAOI drugs.

Flexeril may enhance the effects of alcohol, barbiturates, and other CNS depressants and is closely related to the tricyclic anti-depressants, which have been reported to produce arrhythmias, sinus tachycardia, prolongation of the conduction time leading to MI, and stroke.

Flexeril should be used with caution in patients with a history of urinary retention, angle-closure glaucoma, increased intra-ocular pressure, and in patients taking anticholinergic medication.

The most common adverse events reported in clinical trials with Flexeril 5 mg were drowsiness (29%), dry mouth (21%), and fatigue (6%).

For full prescribing information concerning Flexeril 5 mg, call McNeil Consumer & Specialty Pharmaceuticals at 1-888-440-7903 or visit the product Web site at www.flexeril5mg.com.

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