

SPINE SAFETY NOTICE:

Information for Healthcare Professionals:

Soma® (carisoprodol) Tablets for Oral Use

Important Revisions to the Prescribing Information

According to MedWatch, modifications have been made to the WARNINGS and PRECAUTIONS sections of Soma® (carisoprodol) labeling. The revised WARNINGS and PRECAUTIONS sections address sedation, drug dependence and seizures.

Sedation

Soma® may have sedative properties (in the low back pain trials, 13% to 17% of patients who received Soma experienced sedation compared to 6% of patients who received placebo).

Drug Dependence, Withdrawal and Abuse

In the postmarketing experience with Soma®, cases of dependence, withdrawal, and abuse have been reported with prolonged use. Most cases of dependence, withdrawal, and abuse occurred in patients who have had a history of addiction or who used Soma® in combination with other drugs with abuse potential. Withdrawal symptoms have been reported following abrupt cessation after prolonged use. To reduce the chance of Soma® dependence, withdrawal, or abuse, Soma® should be used with caution in addiction-prone patients and in patients taking other CNS depressants including alcohol, and Soma® should be not be used more than two to three weeks for the relief of acute musculoskeletal discomfort. One of the metabolites of Soma®, meprobamate (a controlled substance), may cause dependence.

Seizures

There have been postmarketing reports of seizures in patients who received Soma®. Most of these cases have occurred in the setting of multiple drug overdoses (including drugs of abuse, illegal drugs, and alcohol).

The complete MedWatch Safety Labeling Changes, including links to prescribing information, are available at:

<http://www.fda.gov/medwatch/SAFETY/2007/sep07.htm>

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a variety of government and other resources for patient safety related notices that may be useful to our members. Information from these notices is also archived

on the NASS Web site at http://www.spine.org/spine_safety_notices.cfm. This information is provided as a service for information and education only.