



SOMA

Soma (carisoprodol), Soma Compound (carisoprodol and aspirin),
Soma Compound w/Codeine (carisoprodol and aspirin and codeine)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Soma, Soma Compound, and Soma Compound with Codeine are centrally acting skeletal muscle relaxants used to relieve discomfort associated with acute, painful musculoskeletal conditions in people 16 years of age or older. Soma, Soma Compound, and Soma Compound with Codeine should only be used for acute treatment periods up to two or three weeks and are not recommended in pediatric patients less than 16 years of age. Soma, Soma Compound and Soma Compound with Codeine have sedative properties and all patients require monitoring for signs of drug dependence, withdrawal, and abuse because of risk for seizures associated with multiple drug overdoses (1-3).

Regulatory Status

FDA-approved indications: Soma, Soma Compound, and Soma Compound with Codeine are indicated for the relief of discomfort associated with acute, painful musculoskeletal conditions in adults (1-3).

Limitations of Use:

Soma should only be used for short periods (up to two or three weeks) (1-3).

Soma is contraindicated in acute intermittent porphyria or hypersensitivity to carbamate such as meprobamate (1-3).

Soma Compound and Soma Compound with Codeine are contraindicated in patients with serious GI complication (i.e., bleeding, perforations, obstruction) due to aspirin use and patients with aspirin induced asthma (a symptom complex which occurs in patients who have asthma, rhino sinusitis, and nasal polyps who develop a severe, potentially fatal bronchospasm shortly after taking aspirin or other NSAIDs) (2-3).

Codeine sulfate has a boxed warning and is contraindicated for postoperative pain management in children who have undergone tonsillectomy and/or adenoidectomy due to respiratory depression in those children who are ultra rapid metabolizers (3).



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Soma agents has been subject to abuse, dependence, withdrawal, misuse, and criminal diversion. Abuse of Soma agents poses a risk of over dosage which may lead to death, CNS and respiratory depression, hypotension, seizures, and other disorders. Withdrawal symptoms have been reported following abrupt cessation of Soma after prolonged use. Reported withdrawal symptoms included insomnia, vomiting, abdominal cramps, headache, tremors, muscle twitching, ataxia, hallucinations, and psychosis. One of Soma's metabolites, meprobamate (a controlled substance), may also cause dependence (1-3).

Soma agents should be used with caution in patients with respiratory depression, seizures, and when used in conjunction with alcohol or other drugs that cause central nervous system depression (1).

Limit the length of treatment to three weeks for the relief of acute musculoskeletal discomfort, keep careful prescription records, monitor for signs of abuse and overdose, and educate patients and their families about abuse and on proper storage and disposal (1-3).

The safety and efficacy of Soma, Soma Compound, and Soma Compound with Codeine in patients under 16 years of age have not been established (1-3).

Summary

Soma, Soma Compound and Soma Compound with Codeine are centrally acting skeletal muscle relaxants used to relieve discomfort associated with acute, painful musculoskeletal conditions in people 16 years of age or older. Concomitant use of CNS depressants such as benzodiazepines, opioids, and tricyclic antidepressants may increase the risk of misuse, drug dependence, withdrawal, and abuse. All patients require monitoring for signs of drug dependence, withdrawal, and abuse because of risk for seizures associated with multiple drug overdoses. The safety and efficacy of Soma in patients under 16 years of age has not been established (1-3).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Soma while maintaining optimal therapeutic outcomes.



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References

1. Soma [package insert]. Somerset, NJ: Meda Pharmaceuticals, Inc.; May 2023.
2. Soma Compound [package insert]. Somerset, NJ: Meda Pharmaceuticals, Inc.; January 2013.
3. Soma Compound w/ Codeine [package insert]. Somerset, NJ: Meda Pharmaceuticals, Inc.; May 2013.