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# Carisoprodol, Aspirin, and Codeine (Soma Compound with Codeine)

??? ??????: 30 ?????2/?????? 2017

To report SUSPECTED ADVERSE REACTIONS, contact Meda Pharmaceuticals Inc. at 1-800-526-3840 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

The following adverse reactions which have occurred with the administration of the individual products alone may also occur with the use of Soma Compound with Codeine (carisoprodol, aspirin, and codeine phosphate tablets). The following events have been reported during post-approval individual use of carisoprodol, aspirin, and codeine. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

## Carisoprodol

).**OVERDOSAGE** Tachycardia, postural hypotension, and facial flushing (see **Cardiovascular**

Drowsiness, dizziness, vertigo, ataxia, tremor, agitation, irritability, headache, depressive reactions, syncope, insomnia, and seizures **Central Nervous System** ).**OVERDOSAGE** (see

Nausea, vomiting, and epigastric discomfort. **Gastrointestinal**

Leukopenia, pancytopenia. **Hematologic**

## Aspirin

The most common adverse reactions associated with the use of aspirin have been gastrointestinal, including both abdominal pain, anorexia, nausea, vomiting, ). Other , **Serious Gastrointestinal Adverse Reactions and PRECAUTIONS, Gastrointestinal Adverse Reactions**WARNINGSgastritis, and occult bleeding (see adverse reactions associated with the use of aspirin include elevated liver enzymes, rash, pruritus, purpura, intracranial hemorrhage, interstitial nephritis, acute renal ).**OVERDOSAGE**failure, and tinnitus. Tinnitus may be a sign of high serum salicylate levels (see

## Codeine Phosphate

Nausea, vomiting, constipation, miosis, sedation, dizziness.

## Drug Abuse And Dependence

).**WARNINGS** Controlled Substance: Schedule C-III (see

**Discontinuation of carisoprodol in animals or in humans after chronic administration can produce withdrawal signs, and there are published case reports of human carisoprodol dependence.**

**In vitro studies demonstrate that carisoprodol elicits barbiturate-like effects. Animal behavioral studies indicate that carisoprodol produces rewarding effects. Monkeys self administer carisoprodol. Drug discrimination studies using rats indicate that carisoprodol has positive reinforcing and discriminating effects similar to barbital, meprobamate, and chlordiazepoxide.**