



CARISOPRODOL (Trade Name: Soma®)

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Introduction:

Carisoprodol is a prescription drug marketed since 1959. It is a centrally acting muscle relaxant. The diversion and abuse of carisoprodol have increased in the last decade.

Licit Uses:

Carisoprodol is used as an adjunct to rest, physical therapy and other measures for relief of acute, painful musculoskeletal conditions. It is available as single-entity tablets containing 250 mg or 350 mg carisoprodol, and as combination tablets containing 200 mg carisoprodol, 325 mg aspirin and 16 mg codeine phosphate. The standard dosage for adults is 250 mg to 350 mg three times daily and at bed-time. Use in patients under age 12 is not recommended. According to IQVIA™, there were approximately 4.2 million prescriptions of carisoprodol products dispensed in the United States in 2017, but actually 4.1 million sold to or picked-up by patients/individuals in 2017 and 3.2 million in 2018.

Chemistry:

Carisoprodol is *N*-isopropyl-2-methyl-2-propyl-1,3-propanediol dicarbamate and is both structurally and pharmacologically related to meprobamate, a schedule IV substance. It has a chemical structure that gives rise to two optical isomers and is typically found as an equal combination of both, which is referred to as a racemic mixture.

Pharmacology:

Carisoprodol does not directly affect skeletal muscle in human. Skeletal muscle relaxant action of carisoprodol may be related to its sedative properties. Recent animal studies conducted under the directive of the National Institute on Drug Abuse (NIDA) indicate that subjective effects of carisoprodol may be similar to other central nervous system depressants such as meprobamate, pentobarbital and chlordiazepoxide. It also possesses rewarding effects. These data suggest that carisoprodol has abuse liability.

The onset of action of carisoprodol is rapid and effects last 4 to 6 hours. It is metabolized in the liver and excreted through kidney. The major metabolic pathway of carisoprodol involves its conversion to meprobamate, a drug with substantial barbiturate-like biological actions. Adverse reactions may include central nervous system related effects such as drowsiness, dizziness, vertigo, ataxia, tremor, agitation, irritability, headache, depressive reactions, syncope and insomnia. Carisoprodol may also adversely affect cardiovascular (tachycardia, postural hypotension and facial flushing), gastrointestinal (nausea, vomiting, hiccup and epigastric distress), and hematologic systems. It may cause idiosyncratic symptoms including extreme weakness, transient quadriplegia, difficulty in

speech, temporary loss of vision, double vision, dilated pupils, agitation, euphoria, confusion, and disorientation. Carisoprodol overdose has resulted in stupor, coma, shock, respiratory depression and death.

Illicit Uses:

Carisoprodol abuse escalated in the last decade in the United States. For the 2012 National Survey on Drug Use and Health (NSDUH) data, 3.69 million people, aged 12 and older, used Soma® for non-medical reasons in their lifetime, which is a significant increase from 3.06 million in 2011. With prolonged abuse at high dosage, carisoprodol can lead to tolerance, dependence and withdrawal symptoms in humans.

Illicit distribution:

According to the Diversion Drug Trends, published by the Drug Enforcement Administration (DEA) on the trends in the diversion of controlled and noncontrolled pharmaceuticals, carisoprodol is one of the most commonly diverted drugs. Diversion and abuse of carisoprodol was prevalent throughout the country. In March 2011, the street prices for Soma® ranged from \$1 to \$5 per tablet. Diversion methods include doctor shopping for the purpose of obtaining multiple prescriptions and forging prescriptions.

The National Forensic Laboratory Information System (NFLIS) is a DEA database that collects scientifically verified data on drug items and cases submitted to and analyzed by federal, state, and local forensic laboratories, including DEA laboratories. In 2013, there were 3,847 substances compared to 1,735 substances in 2017, (and, preliminary, 1,305 substances in 2018) identified by federal, state, and local forensic laboratories as carisoprodol. Until 2014, according to NFLIS, carisoprodol was consistently in the top 25 most frequently identified drugs by the state and local forensic laboratories since 2000.

The American Association of Poison Control Centers reported a total of 2,236 carisoprodol case mentions, 901 single exposures, and two related death in 2017.

Control status:

Carisoprodol is a schedule IV controlled substance under the Controlled Substances Act.

Comments and additional information are welcomed by the Drug and Chemical Evaluation Section; Fax 571-362-4250, Telephone 571-362-3249, or Email DPE@usdoj.gov.