



CARISOPRODOL (Trade Name: Soma®)

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DEA/OD/ODE

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 IMS Health™, there were approximately 11.1 million prescriptions for carisoprodol dispensed in 2010 and 2.8 million dispensed in the first quarter of 2011.

Chemistry/Pharmacology:

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. Carisoprodol does not directly affect skeletal muscle in man. 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 and it 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, head ache, 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, ataxia, 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 has escalated in the last decade in the United States. According to 2009 National Survey on Drug Use and Health (NSDUH) data, 2.95 million people, aged 12 and older, used Soma® for non-medical reasons in their lifetime. 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 continues to be one of the most commonly diverted drugs. Diversion and abuse of carisoprodol is prevalent throughout the country. As of March 2011, 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 state and local forensic laboratories. The System to Retrieve Information from Drug Evidence provides information on drug seizures reported to and analyzed by DEA laboratories. Substances identified by federal, state and local forensic laboratories, as carisoprodol, increased from 3,988 in 2008 to 5,076 in 2010. In the first quarter of 2011, 870 exhibits were identified as carisoprodol. According to NFLIS, carisoprodol has been 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 8,976 total carisoprodol exposures, 3,685 single exposures and 2 related deaths in 2009. Medical Examiners Commission Reports released by the Florida Department of Law Enforcement (FDLE) indicate that carisoprodol/meprobamate related deaths in Florida increased by more than 100% from 208 in 2003 to 455 in 2009, surpassing opioids such as heroin, fentanyl, and hydromorphone. In the first six months of 2010, 220 deaths were related to carisoprodol/meprobamate.

Control status:

As of January 11, 2012, Carisoprodol is a schedule IV controlled substance under the Controlled Substances Act of 1970.

Comments and additional information are welcomed by the Drug and Chemical Evaluation Section, Fax 202-353-1263, telephone 202-307-7183, or Email ODE@usdoj.gov.