Drug Enforcement Administration
Office of Diversion Control
Drug & Chemical Evaluation Section

CYCLOBENZAPRINE
(Brand Name: Flexeril®, Amrix®)

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Introduction:

Cyclobenzaprine is a central nervous system (CNS) muscle relaxant intended for short-term use in the treatment of pain, tenderness, and limitation of motion caused by muscle spasms. Cyclobenzaprine may enhance the effects of other CNS depressants including alcohol, barbiturates, benzodiazepines and narcotics and anecdotal reports indicate it is used non-medically to induce euphoria and relaxation. Cyclobenzaprine is not controlled under the Controlled Substances Act (CSA).

Licit Uses:

Cyclobenzaprine hydrochloride is approved for use in the United States as a muscle relaxant. It is marketed under the brand names Flexeril® and Amrix® and also as generic formulations in 5, 7.5, and 10 mg tablets intended for short-term (2 to 3 week) oral administration. The usual starting dose is 5 mg, three times per day. The maximum recommended dose is 10 mg, three times daily. IMS Health™ reports 25.2 million total prescriptions of cyclobenzaprine dispensed in the U.S. in 2011 and 13.0 million prescriptions dispensed in the first six months of 2012.

Chemistry and Pharmacology:

Cyclobenzaprine Hydrochloride is a white crystalline tricyclic amine salt that is freely soluble in water or alcohol. Cyclobenzaprine has been shown to reduce or abolish skeletal muscle hyperactivity. It is thought to act within the CNS at the brain stem rather than spinal cord levels, although action at the spinal cord level may contribute to some of its skeletal muscle relaxant action. Pharmacological studies in animals have shown a similarity between the effects of the structurally-related tricyclic antidepressants and cyclobenzaprine. The most frequently encountered adverse effects of cyclobenzaprine include the anticholinergic effects, such as, drowsiness, dry mouth and dizziness. Other CNS effects include blurred vision, confusion, anxiety, agitation, psychosis, abnormal thinking, and hallucinations. Cardiovascular effects include increased heart rate and palpitations.

The induction of these effects is dose-dependent. Nausea, headache and malaise may be experienced upon abrupt termination of prolonged use.

Abuse and Diversion:

Several indicators suggest that cyclobenzaprine is being intentionally misused or abused. According to the American Association of Poison Control Centers, 10,529 case mentions and 4,607 single exposures were associated with cyclobenzaprine in 2010. The poison cases resulted in 72 major medical outcomes. There were an estimated 12,411 emergency room visits associated with cyclobenzaprine in 2010, a statistically significant increase (101%) from 6,183 visits in 2004 (New DAWN ED).

According to the National Forensic Laboratory Information System (NFLIS) and the System to Retrieve Information from Drug Evidence (STRIDE), there were 1,360 cyclobenzaprine reports from Federal, state and local forensic laboratories in 2011 and in the first six months of 2012, there were 635 cyclobenzaprine reports.

Anecdotal reports found on the Internet suggest that individuals are taking cyclobenzaprine alone or in combination with other illicit drugs to produce or enhance psychoactive effects. Individuals have reported taking cyclobenzadrine both orally and intranasally at doses ranging from 10 mg to 60 mg. Sedation, relaxation and increased heart rate were the most common effects reported. Euphoria was reported by a smaller number of individuals.

Control Status:

Cyclobenzaprine is not currently controlled under the Controlled Substances Act.

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.