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

METHYLPHENIDATE

(Trade Names: Ritalin- (IR, LA, and SR), Concerta, Metadate- (CD and ER), Methylin- (IR and ER) and Focalin- (IR and ER))

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DEA/OD/ODE

Introduction:

Methylphenidate (methyl-alpha-phenyl-2-piperidine-acetate hydrochloride) is a central nervous system (CNS) stimulant that has been marketed in the United States since the 1950s. For many years, Ritalin® (immediate release (IR) product), was the only brand-name product available. In recent years, other IR, extended release (ER), and long acting (LA) methylphenidate products have entered the market. These products are primarily prescribed to children for the treatment of attention deficit hyperactivity disorder (ADHD).

Domestic and worldwide use of methylphenidate has increased dramatically since 1990. According to the United Nations International Narcotic Control Board (INCB) report, the United States is the main consumer of methylphenidate accounting for about 69 percent of the global medical use of methylphenidate in 2011.

Licit Use:

Methylphenidate is used almost exclusively for the treatment of ADHD. There is a considerable body of literature on the short-term efficacy of methylphenidate pharmaco-therapy for the treatment of ADHD. However, attentional improvement is not diagnostic of ADHD. There is no diagnostic test that can confirm an ADHD diagnosis.

Recent data suggests that some children may continue to have significant ADHD-symptoms into adulthood. As a consequence, the prescription of methylphenidate for individuals 18 and older is the most rapidly growing market. Longer acting products, primarily Concerta®, have gained a significant share of the total methylphenidate market. The IMS Health National Prescription Audit *Plus*™ reported 15.7 million methylphenidate prescriptions dispensed in 2011 and 16.3 million dispensed in 2012.

Chemistry/Pharmacology:

Methylphenidate is a CNS stimulant and produces a number of effects including appetite suppression, increased alertness and increases in blood pressure, heart rate, respiration, and body temperature. Almost complete absorption of IR methylphenidate occurs after oral administration with peak plasma levels in about 2 hours. It is extensively metabolized and about 80% of the dose is excreted in the urine as ritalinic acid. Only 20% of the administered oral dose is bioavailable due to extensive first-pass metabolism.

Biochemically, methylphenidate enhances the release and blocks the reuptake of dopamine (DA) and norepinephrine (NE) in mammalian brain. Pharmacologically methylphenidate is most closely related to cocaine. In human subjects, methylphenidate binds to the same receptor sites as cocaine in the brain and produces effects that are indistinguishable from cocaine.

Illicit Use:

Like other potent stimulants, methylphenidate is abused for its "feel good" stimulant effects. The occasional abuser may use methylphenidate as a study aid to increase attention and stay awake. Others may use methylphenidate recreationally and combine it with alcohol or some other depressant to feel more alert or less drunk. Serious methylphenidate abusers often snort or inject methylphenidate for its intense euphoric effects or to alleviate the severe depression and craving associated with a stimulant withdrawal syndrome.

Monitoring the Future (MTF) is a National Institute on Drug Abuse (NIDA) funded study conducted by the University of Michigan. In 2012, the MTF survey indicated that 0.7% of 8th grade students, 1.9% of 10th grade students and 2.6% of 12th grade students reported nonmedical use of Ritalin® in the past year.

The National Survey on Drug Use and Health (NSDUH) is a database that measures drug use by non-institutionalized people aged 12 or older living in the U.S. In 2011, 4.9% of 18-25 year olds reported non-medical use of methylphenidate or Ritalin® in their lifetime. An estimated 4.9 million people (1.9% of the population) aged 12 years of older used methylphenidate or Ritalin® for non-medical purposes in their lifetime, according to the 2011 NSDUH report.

The American Association of Poison Control Centers (AAPCC) report indicates that in 2011, there were a total of 9,798 methylphenidate exposures. Of this total, 5,341 were unintentional exposures and 1,189 were intentional. According to the Drug Abuse Warning Network (DAWN ED), nonmedical use of methylphenidate accounted for an estimated 4,778 visits to the emergency department in 2010. The number of emergency department visits associated with nonmedical use of methylphenidate increased to 6,395 in 2011.

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 (STRIDE) provides information on drug seizures reported to and analyzed by DEA laboratories. Of the substance exhibits submitted to federal, state and local forensic laboratories in 2010, there were 2,224 identified as methylphenidate. There were 2,300 exhibits in 2011 and 2,164 exhibits in 2012 which were identified as methylphenidate.

User Population:

While a wide spectrum of the population has abused methylphenidate products, the primary abusers are individuals younger than 25 years of age; who often obtain methylphenidate from a friend or classmate and use this drug as a study aid or to party.

Illicit Distribution:

Unlike other potent stimulants, there is no clandestine production of methylphenidate and diverted pharmaceutical products are the only source for abuse purposes. Methylphenidate is obtained from fraudulent prescriptions, doctor shopping, pharmacy theft and from friends or associates who have obtained the drug through a prescription.

Control Status:

Methylphenidate is a Schedule II substance under the Controlled Substances Act.

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