



DEC 12 2007

Dear Colleague:

On December 11, 2007, the Drug Enforcement Agency (DEA) released an Advisory Notice reporting that as of January 1, 2008, the distribution of methadone hydrochloride tablets, 40 mg (dispersible), will be limited to facilities authorized for detoxification and maintenance treatment of opioid addiction. This dosage formulation will no longer be distributed to retail pharmacies. (see http://www.dea.gov/diversion.usdoj.gov/pubs/pressrel/methadone_advisory.htm). Methadone hydrochloride tablet, 40 mg (dispersible), is also known by the tradename Disket[®].

The 40-mg dispersible tablets are approved only for the use of detoxification and maintenance treatment of opioid addiction. According to the methadone package insert, “[m]ethadone products when used for the treatment of opioid addiction in detoxification or maintenance programs, shall be dispensed only by opioid treatment programs (and agencies, practitioners or institutions by formal agreement with the program sponsor) certified by the Substance Abuse and Mental Health Services Administration and approved by the designated state authority.” Therefore, the methadone 40-mg dispersible tablets should only be obtainable through SAMHSA certified opioid treatment programs.

Although available data cannot distinguish the possible roles of the 40-mg dispersible tablet from other dosage forms in the increased number of reported methadone-associated deaths, this action will help control the amount of methadone being diverted by reducing the number of distribution points.

For additional information or questions, please contact Jennifer Fan, Pharm.D., J.D., Public Health Advisor, at (240) 276-1759 or by e-mail at Jennifer.fan@samhsa.hhs.gov.

Sincerely,

H. Westley Clark, M.D., J.D., M.P.H., CAS, FASAM
Director
Center for Substance Abuse Treatment

Enclosure



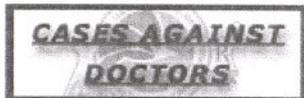
- DIVERSION PROGRAMS
- APPLICATIONS & ON-LINE FORMS
- ARCOS
- CHEMICALS
- CONTROLLED SUBSTANCE SCHEDULES
- CSOS
- IMPORT AND EXPORT
- NFLIS
- QUOTAS
- REGISTRATION SUPPORT
- REPORTS REQUIRED BY 21 CFR

RESOURCES

- CAREER OPPORTUNITIES
- DRUGS/CHEMICALS OF CONCERN
- e-COMMERCE INITIATIVES
- FEDERAL REGISTER NOTICES
- MEETINGS & EVENTS
- OFFICES & DIRECTORIES
- PROGRAM DESCRIPTION
- PUBLICATIONS
- QUESTIONS & ANSWERS
- REGULATIONS & CODIFIED CSA
- SIGNIFICANT GUIDANCE DOCUMENTS

LINKS

- FEDERAL AGENCIES & RELATED
- INDUSTRY RELATED
- PUBLIC INTEREST



[Pubs](#) > [Press Releases](#) > [Methadone Hydrochloride Tablets USP 40 mg \(Dispersible\)](#)

Advisory

Methadone Hydrochloride Tablets USP 40 mg (Dispersible)

As of January 1, 2008, manufacturers of methadone hydrochloride tablets 40 mg (dispersible) have voluntarily agreed to restrict distribution of this formulation to only those facilities authorized for detoxification and maintenance treatment of opioid addiction, and hospitals. Manufacturers will instruct their wholesale distributors to discontinue supplying this formulation to any facility not meeting the above criteria.

Methadone is a long-lasting opioid medication used in the treatment of pain and narcotic addiction. The 5mg and 10 mg formulations indicated for the treatment of pain will continue to be available to all authorized registrants, including retail pharmacies. The 40 mg methadone formulation is indicated for the detoxification and maintenance treatment of opioid addiction. The 40 mg strength is not FDA approved for use in the management of pain. Thus, the distribution and availability of the 40 mg formulation will be limited to registrants in only those settings using the 40 mg formulation for the appropriate indication.

The DEA and pharmaceutical industry agree that the reported increase in methadone-related adverse events merits action and further agree to a united effort to assure that methadone is properly distributed, consistent with its approved uses. Industry and the federal entities involved commit to monitor the progress of this initiative.