

Methadone Hydrochloride Tablets USP 40 mg (Dispersible)

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The federal Drug Enforcement Agency has issued the following Advisory as of December 6, 2007:

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.