

# MARINOL<sup>®</sup> (dronabinol) Capsules CIII Rescheduling Fact Sheet

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All drugs regulated under the Controlled Substances Act (CSA) are placed into one of five schedules. Schedule I is reserved for the drugs with the greatest potential for abuse and that have no recognized medical use, while Schedule V is for drugs with the least potential for abuse. A drug receives a specific placement after being reviewed for the substance's accepted medical use and potential for abuse or addiction<sup>1</sup>.

In 1999, the U.S. Drug Enforcement Administration (DEA), based in part from a concurring recommendation from the U.S. Department of Health and Human Services, reclassified MARINOL<sup>®</sup> (dronabinol) Capsules from a Schedule II controlled substance to Schedule III. This action was taken after thorough review of the abuse potential of MARINOL<sup>®</sup>, which found that the drug has lower abuse and addiction potential than drugs or substances in Schedules I and II<sup>2</sup>. The DEA also found little evidence of actual MARINOL<sup>®</sup> abuse, despite an increased number of prescriptions issued<sup>3</sup>.

## **Schedule III Benefits<sup>2</sup>:**

As a Schedule III drug, MARINOL<sup>®</sup> is more accessible to patients, and simpler for physicians to prescribe and pharmacists to dispense:

- Physicians can phone in prescriptions to pharmacies.
- Patients are allowed five prescription refills over a period of six months.
- Pharmacists can simplify record keeping.

## **State Regulations<sup>2</sup>:**

*For physicians to prescribe MARINOL<sup>®</sup> as a Schedule III product, each state also must approve the rescheduling. Following is a list of states that have approved MARINOL<sup>®</sup> as a Schedule III product:*

Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, North Dakota, New York, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming

*As of September 2003, Oklahoma is the only state that has not yet adopted the federal rescheduling decision.*

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<sup>1</sup> *Controlled Substances Act*, 2 U.S.C Section 801 (a), 811, 812.

<sup>2</sup> "Schedules of Controlled Substances: Rescheduling of the Food and Drug Administration Approved Product Containing Synthetic Dronabinol [D-9-(trans) - Tetrahydrocannabinol] in Sesame Oil and Encapsulated in Soft Gelatin Capsules From Schedule II to Schedule III" 64 Fed Reg 35928 - 35930 (July 2, 1999).

<sup>3</sup> 63 Fed. Reg. 59751 (Nov. 5, 1998)