

Syndros (Dronabinol) Oral Solution Approved

July 7, 2016

The U.S. Food and Drug Administration (FDA) has approved Syndros (dronabinol) Insys Therapeutics' oral solution for the treatment of anorexia associated with weight loss in patients with AIDS, and nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments. Syndros is currently awaiting scheduling by Drug Enforcement Administration.

Healthcare professionals and patients are encouraged to report any adverse events or side effects related to the use of this product and/or quality problems to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- ✓ Complete and submit the report online: www.fda.gov/MedWatch/report.htm
- ✓ Complete and return a form by mail (address on the pre-addressed form) or fax (1-800-FDA-0178).
[Call 1-800-332-1088 to request a reporting form or download a form at
<http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm>.]

Source: Facts and Comparisons

For additional information: http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/103976s5225lbl.pdf