

Soma® (carisoprodol) Reclassified to Schedule IV

IMPORTANT NOTICE

On December 12, 2011, the Drug Enforcement Administration announced its final rule in the Federal Register (76 Fed. Reg. 77,330) indicating that carisoprodol products would be reclassified to schedule IV (controlled) status according to the Controlled Substances Act. As of January 12, 2012, carisoprodol will be considered a schedule IV substance in all 50 states.

BACKGROUND

Originally approved in 1959, Soma (carisoprodol) is a skeletal muscle relaxant currently classified as a scheduled (controlled) medication in only a handful of states. On December 12, 2011, the DEA published a final rule indicating that all carisoprodol products would be reclassified as schedule IV controlled substances as of January 12, 2012, regardless of the dispensing state. The reclassification of carisoprodol into controlled substance status translates into a variety of changes regarding how the medication must be manufactured, distributed, and dispensed.

The DEA's final rule indicates that manufacturers, distributors, dispensers, and any person or institution performing research on or conducting business in possession of carisoprodol must apply for registration with the DEA by January 11, 2012; although, current activities may continue until an approval or denial has been received by the recipient from the DEA. If registration is not achieved or desired, all stock of carisoprodol must be surrendered or transferred to a DEA registrant authorized to possess schedule IV products. In addition to the restrictions above, manufacturers will be mandated to include the "C-IV" mark on all commercial containers for carisoprodol products after April 10, 2012. Due to its new classification as a schedule IV product, a maximum of six fills per prescription (i.e. initial fill plus five total refills) will be allowed according to current restrictions from the Controlled Substances Act. Furthermore, prescriptions for carisoprodol will only be valid for a period of six months from the date the prescription was written.

PMSI Actions

Per recommendations from PMSI's Pharmacy and Therapeutics (P&T) committee, carisoprodol is being considered for removal from PMSI's chronic workers' compensation formulary offerings. Carisoprodol will remain on acute formulary offerings in accordance with current clinical practice recommendations. Processing of prescriptions for carisoprodol via PMSI's Mail Order Pharmacy will be conducted in accordance with all regulations as dictated by federal law. According to PMSI's 2011 Annual Drug Trends Report, carisoprodol accounted for 2.2 % of all transactions, by volume, making it the 11th most commonly utilized medication in our patient population.



Patient Actions

At this time, no action is required on behalf of patients possessing a valid prescription for carisoprodol or legally using carisoprodol according to established medical practices. On or after January 12, 2012, patients will continue to be able to fill prescriptions for all carisoprodol products; however, the number of fills per prescription will be limited to a total of six fills (i.e. initial fill plus five refills). After a total of six fills or after six months, a new prescription will be required for continued use of carisoprodol products.

ALTERNATIVE PRODUCTS

A number of alternative skeletal muscle relaxants are available, all of which remain as non-scheduled (non-controlled) substances; and therefore, are not subject to restrictions from the Controlled Substances Act. A short listing of alternatives is provided below:

Alternative Agents	Average Cost per Day of Supply
Lioresal® (baclofen)	\$0.96
Flexeril® (cyclobenzaprine)	\$2.55
Zanaflex® (tizanidine)	\$4.41
Skelaxin® (metaxalone)	\$11.22

Note: Prices based on average daily dose and average wholesale price (AWP) for generic alternatives, where available. Average cost per day of supply should be compared to an estimated daily cost per day of supply of generic carisoprodol 350 mg of \$0.57, and Soma 250 mg at \$15.81.

CONCLUSION

This PMSI Drug Alert is made available by our clinical pharmacist team to provide you pertinent drug information and identify the potential impact on your injured workers’ care and your costs. As your pharmacy partner, PMSI understands the importance of staying on top of breaking news in the pain management arena and keeping you informed. We will continue to monitor and regularly communicate our proactive response to FDA recommendations to help protect your interests.

DISCLAIMER

This publication is provided as reference material and is based in part on information derived from third parties. PMSI does not assume liability or responsibility for the accuracy or completeness of any third-party material in this document. The information contained herein should not be construed as an endorsement of any kind. This document is advisory in nature only and does not replace sound clinical judgment or individualized patient care in the delivery of drug therapy.

REFERENCES

DEA Federally Controls Carisoprodol as a Schedule IV Substance, Establishes Regulatory Timeline.
http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2011/12/dea-federally-controls-carisoprodol-as-a-schedule-iv-substance-establishes-regulatory-timeline.html <Accessed December 29, 2011>

Schedules of Controlled Substances: Placement of Carisoprodol into Schedule IV. U.S. Department of Justice Drug Enforcement Administration.
http://www.deadiversion.usdoj.gov/fed_regs/rules/2011/fr1212_10.htm <Accessed December 29, 2011>

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