

Re: Return of Yellow-Square Mysoline® (primidone, USP) 250 mg tablets  
Date: June 29, 2009

Dear Physician,

We are writing to inform you that Valeant is now able to reintroduce the previous formulation/presentation of yellow-square Mysoline 250 mg tablets. You may have noticed that for the past year, Valeant had switched to a temporary version of branded Mysoline 250 mg tablets, presented as a white-round tablet manufactured by Watson Laboratories. From this point forward, the yellow-square version will be the only branded version of Mysoline 250 mg tablets manufactured. There will, however, be a brief transition overlap period during which both the white-round 250 mg tablet and yellow-square 250 mg tablet may both be available in pharmacies. Following this period, only the yellow-square 250 mg tablet will be available as Mysoline 250 mg tablets.

Mysoline tablets are indicated in the control of grand mal, psychomotor and focal epileptic seizures.

Listed below is important information regarding this change to Mysoline 250 mg tablets:

- Temporarily presented (for approximately the past year) as white-round tablets, Mysoline 250 mg will once again be presented as a yellow-square shaped tablet
- The bottle will be in Valeant trade packaging, will include the call out: "Original Tablet Design" on the bottle, and will also feature a picture of the yellow-square tablet
- The NDC number 66490-691-10 will remain unchanged
- FDA has reviewed and approved this change


The current changes in manufacturing affect the Mysoline 250 mg tablets only, and production of Mysoline 50 mg tablets remains unaffected by the changes outlined above.

As is customary, when any changes occur with anticonvulsant therapy, we suggest that patients receive additional counseling from their physicians.

If your patients are seeking additional information on this issue, we have established a website at [www.valeant.com/mysoline](http://www.valeant.com/mysoline) to further address their (or your) questions. Questions may also be directed to Valeant's Customer Service team at 800-556-1937.

Valeant is committed to maintaining the very highest quality standards for the medications we offer in epilepsy care, and is pleased to be able to re-release this original formulation of Mysoline 250 mg tablets.

Sincerely,



Janet MJ Hammond, MD, PhD, ScM  
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North America, Research and Development  
Valeant Pharmaceuticals International