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SAVIENT

PHARMACEUTICALS, INC.

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Dear Healthcare Professional:

Savient Pharmaceuticals, Inc. would like to inform you of new, clinically important, information regarding Oxandrin[®] (oxandrolone, USP) CIII.

Oxandrin[®], a synthetic derivative of testosterone, is indicated as adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma, and in some patients who without definite pathophysiologic reasons fail to gain or to maintain normal weight, to offset the protein catabolism associated with prolonged administration of corticosteroids, and for the relief of the bone pain frequently accompanying osteoporosis.

Anabolic androgenic steroids as a class may increase susceptibility to oral anticoagulants, with reduction of the anticoagulant dosage to maintain the desired prothrombin time (PT). Data from a recent clinical study allows more specific guidance for concurrent use of Oxandrin[®] and warfarin. **This information is being sent to you in advance of the printing of the new Package Inserts incorporating the new content.**

Precautions: Concurrent dosing of oxandrolone and warfarin may result in unexpectedly large increases in the International Normalized Ratio (INR) or PT. When oxandrolone is prescribed to patients being treated with warfarin, doses of warfarin may need to be decreased significantly to maintain a desirable INR level and diminish the risk of potentially serious bleeding.

Information for patients: The physician should instruct patients to report immediately any use of warfarin and any bleeding.

Drug Interaction: Warfarin -- A multidose study of oxandrolone, given as 5 or 10 mg BID in 15 healthy subjects concurrently treated with warfarin, resulted in a mean increase in S-warfarin half-life from 26 to 48 hours and AUC from 4.55 to 12.08 ng*hr/mL; similar increases in R-warfarin half-life were also detected. Microscopic hematuria (9/15) and gingival bleeding (1/15) were also observed. **A 5.5 fold decrease in the mean warfarin dose from 6.13 mg/day to 1.13 mg/day (approximately 80-85% reduction of warfarin dose) was necessary to maintain a target INR of 1.5.** When oxandrolone therapy is initiated in a patient already receiving treatment with warfarin, the INR or PT should be monitored closely and the dose of warfarin adjusted as necessary until a stable INR or PT has been achieved. Furthermore, in patients receiving both drugs, careful monitoring of the INR or PT, and adjustment of the warfarin dosage if indicated, are recommended when the oxandrolone dose is changed or discontinued. Patients should be closely monitored for signs and symptoms of occult bleeding.

Oxandrin[®] is available in 2.5 mg and 10 mg tablets. Please see full prescribing information in the enclosed current Package Insert (see reverse).

Respectfully,

Faith D. Ottery MD

Faith D. Ottery, MD, PhD
Director, Medical Affairs