

CHART A

	Savient Pharmaceuticals OXANDRIN®	Sandoz GMBH OXANDROLONE (ANDA #076897)	Upsher-Smith Labs OXANDROLONE (ANDA # 076761)
Comparisons:			
Indications & Usage:	Oxandrin 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 (See DOSAGE AND ADMINISTRATION).	Oxandrolone Tablets, USP are indicated as adjunctive therapy to offset the protein catabolism associated with prolonged administration of corticosteroids, and for the relief of the bone pain frequently accompanying osteoporosis (see DOSAGE AND ADMINISTRATION).	Oxandrolone is indicated as adjunctive therapy to offset the protein catabolism associated with prolonged administration of corticosteroids, and for the relief of the bone pain frequently accompanying osteoporosis (see DOSAGE AND ADMINISTRATION).
Geriatric Use:	Oxandrin, at daily doses of 5 mg bid and 10 mg bid, was evaluated in four clinical trials involving a total of 339 patients with different underlying medical conditions. The maximum duration of treatment was 4 months with the average duration of treatment from 68.5 days to 94.7 days across the studies. A total of 172 elderly patients (≥ 65 years of age) received Oxandrin treatment. Mean weight gain was similar in those ≥ 65 and those < 65 years of age. No significant differences in efficacy were detected between the 5 mg bid and 10 mg bid daily doses. The adverse event profiles were similar between the two age groups although the elderly, particularly in women, had a greater sensitivity to fluid retention and increases in hepatic transaminases. A single dose pharmacokinetic study in elderly volunteers revealed an increased half-life when compared to younger volunteers. (see CLINICAL PHARMACOLOGY) Based on greater sensitivity to drug-induced fluid retention and transaminase elevations, a lower dose is recommended in the elderly (see DOSAGE AND ADMINISTRATION).	Certain geriatric use information is protected by market exclusivity	Certain geriatric use information is protected by market exclusivity
Geriatric dosing	Recommended dose for geriatric patients is 5 mg bid.	None	None