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Dispensing Errors Of Zanaflex Tablets Prompt Expanded Education Campaign

Acorda is sending a second letter to pharmacies alerting them to possible dispensing errors between ***Zanaflex*** capsules and tablet versions of tizanidine.

The capsules and tablets (which have gone generic) of the spasticity agent are not AB-rated, and Acorda has been receiving reports of pharmacies filling scripts for capsules with tablets.

Although the dosage forms are bioequivalent in the fasted state, "pharmacokinetic studies show that Zanaflex cpsules have a different pharmacokinetic profile when given with food," the FDL-1draft letter notes.

Administration of the tablets with food increases mean maximal plasma concentration by approximately 30%, while taking capsules with food results in a 20% decrease in concentration.

Acorda's launch of the capsules in April featured a letter to healthcare professionals, including approximately 65,000 pharmacies. The FDL-2April letter noted that switching dosage forms or changing administration between fed and fasted states within a dosage form could cause adverse events and affect onset of action.

The draft letter, which is being sent to pharmacies that have dispensed tizanidine in the last 12 months, emphasizes that " any switch in dose, administration, or formulation should only be in consultation with the prescribing physician."

Acorda has also prepared a consumer sheet and is working with chain pharmacies to generate internal reminders about the issue.

The company is running a sampling program as part of the launch of Zanaflex capsules and notes in the draft letter that "the greatest potential for adverse events may occur when switching from Zanaflex Capsules to a tablet formulation when given with food."

Generic tizanidine tablets entered the market in 2002. Acorda developed the capsule formulation to address adverse event issues related to the tablets, such as somnolence. The label does not differentiate the dosage forms on that issue, but the company is considering a registry or clinical trial program to further establish differences between the products.

The capsule was also developed to allow sprinkling on apple sauce for patients who have trouble swallowing, although that administration is not bioequivalent to taking an intact capsule under fasted conditions.

- M. Nielsen Hobbs