Ensure Zanaflex Capsules™ (tizanidine hydrochloride) Prescriptions are Filled Correctly

Zanaflex Capsules™ 2 mg 4 mg 6 mg
(tizanidine hydrochloride)

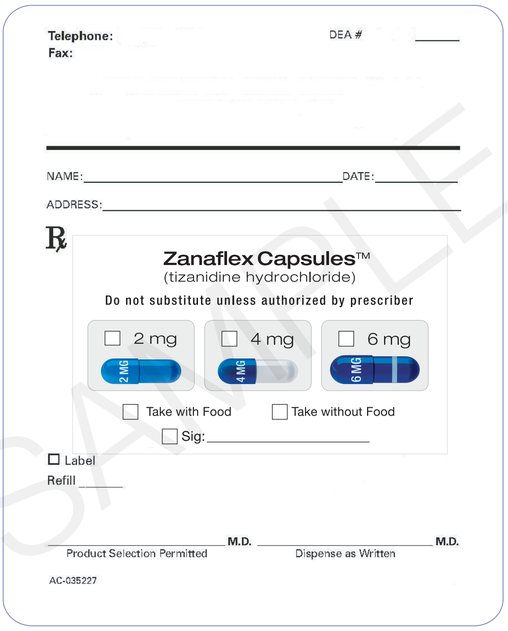
Zanaflex Capsules are **Single Source Product** and **not AB rated**.

Zanaflex Capsules are not bioequivalent to Zanaflex or tizanidine tablets.

IMPORTANT PHARMACOKINETIC DIFFERENCES EXIST BETWEEN ZANAFLEX CAPSULES AND TIZANIDINE HYDROCHLORIDE.[1]

Please do not mistakenly substitute prescriptions written for Zanaflex Capsules with tablets.

Substitutions should not be made unless authorized by the prescriber.



Dispense Zanaflex Capsules™ as Written.

www.ZanaflexCapsules.com

ACORDA THERAPEUTICS

ZC00096

Please see below for Important Safety Information

Important Safety Information

- Use with fluvoxamine or ciprofloxacin is contraindicated and results in significant increases in tizanidine plasma levels.
- There is a limited data base for chronic use of single doses above 8 mg and multiple doses above 24 mg per day.
- Tizanidine is an α2-adrenergic agonist and can produce hypotension. In a single-dose study where patients were not titrated, two-thirds of patients given 8 mg of Zanaflex® (tizanidine hydrochloride) experienced hypotension, which may be minimized by titration of dose. The hypotensive effect is dose related and has been measured following single doses of α2 mg.
- Tizanidine occasionally causes liver injury, most often of the hepatocellular type. In controlled clinical studies, approximately 5% of patients treated with tizanidine had elevations of liver enzyme tests (ALT, AST). Monitoring of these levels is recommended during the first 6 months of treatment (baseline, 1, 3 and 6 months) and periodically thereafter. Most cases resolve rapidly upon drug withdrawal with no reported residual problems.
- Because of the potential toxic hepatic effect of tizanidine, the drug should be used only with extreme caution in patients with impaired hepatic function.
- Patients should be advised that sedation may interfere with daily activities. These effects appear to be dose related.
- Visual hallucinations or delusions occurred in 3% (5/170) of study patients in two North American clinical trials.
- Use with caution in patients with renal impairment.
- Use with oral contraceptives results in 50% decrease in tizanidine clearance.
- To discontinue therapy, taper the dose in patients receiving high doses over long time periods to reduce the risk of hypertension, tachycardia and hypertonia.
- In vitro studies indicate that tizanidine and the major metabolites are not likely to affect the metabolism of other drugs metabolized by cytochrome P450 isoenzymes.
- Most common adverse events with tizanidine include dry mouth (49%), somnolence (48%), asthenia [weakness, fatigue and/or tiredness] (41%), dizziness (16%) and increased ALT (5%). Other adverse events include UTI, infection and constipation.
- Food has complex effects on tizanidine pharmacokinetics, which differ for with the different formulations. These pharmacokinetic differences may result in clinically significant differences when switching formulations, or changing administration during a fed or fasted state. These changes may result in increased adverse events or a delayed/more rapid onset of activity, depending on the nature of the switch.

References

1. Zanaflex Capsules Package Insert. Acorda Therapeutics, Inc. Hawthorne NY, Jul. 2006.

Before prescribing, please see accompanying full prescribing information or visit www.ZanaflexCapsules.com