



## **TIZANIDINE POWDER (tizanidine)**

### **RATIONALE FOR INCLUSION IN PA PROGRAM**

#### **Background**

Tizanidine is a skeletal muscle relaxant that for the management of spasticity, muscle spasms related to neurological conditions such as spinal cord injury and multiple sclerosis (1).

Zanaflex (tizanidine) tablets are available in two strengths as white uncoated tablets containing tizanidine hydrochloride 2 mg or 4 mg. The capsules are available in three strengths as two-piece hard gelatin capsules containing tizanidine hydrochloride 2 mg, 4mg, or 6 mg (1).

#### **Regulatory Status**

FDA-approved indication: Tizanidine is a short-acting drug for the management of spasticity. Because of the short duration of effect, treatment with tizanidine should be reserved for those daily activities and times when relief of spasticity is most important (1).

There is a potential interaction with ciprofloxacin or fluvoxamine. In a pharmacokinetic study, tizanidine serum concentrations were significantly increased AUC 33-fold when taken with fluvoxamine and AUC 10-fold when concomitantly taken with ciprofloxacin. Clinically significant hypotension (decreases in both systolic and diastolic pressure) has been reported with concomitant administration of either fluvoxamine or ciprofloxacin and single doses of 4 mg of tizanidine. Therefore, concomitant use of tizanidine with fluvoxamine or with ciprofloxacin, potent inhibitors of CYP1A2, is contraindicated (1).

There are no adequate and well-controlled studies to document the safety and efficacy of tizanidine in children (1).

Off-label (non-FDA approved) compounded topical preparations of tizanidine have not been proven to be safe or effective.

#### **Summary**

Tizanidine is a short-acting drug for the oral administration for the management of spasticity. Because of the short duration of effect, treatment with tizanidine should be reserved for those daily activities and times when relief of spasticity is most important. There are no adequate and well-controlled

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studies to document the safety and efficacy of tizanidine in children (1).

Prior approval is required to ensure the safe, clinically appropriate and cost-effective use of Tizanidine powder while maintaining optimal therapeutic outcomes.

**References**

1. Zanaflex [package insert]. Zug, Switzerland: Covis Pharma; December 2020.