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For further information regarding Indication, **Boxed WARNING** and other Important Safety Information for NUPLAZID, please click here: <u>Prescribing Information</u>.



NUPLAZID® (pimavanserin): Effect of Crushing Tablets

This letter is being provided based on your specific request for information on the effect of crushing pimavanserin tablets.

Relevant Labeling Information¹

• NUPLAZID is available as 34 mg capsules and 10 mg tablets.

Summary

- There is no data looking specifically at the pharmacokinetic (PK) parameters of crushed pimavanserin tablets.
- However, because pimavanserin is supplied as an immediate-release formulation,¹ no changes to PK parameters would be expected.

Background

The PK profile of pimavanserin has been evaluated in healthy participants as well as in patients with Parkinson's disease (PD). The PK of pimavanserin is similar in both the PD population, and healthy subjects.¹ The median T_{max} of pimavanserin was 6 (range 4-24) hours and was generally unaffected by dose. The bioavailability of pimavanserin oral tablet and pimavanserin solution was essentially identical.^{1,2} Participants who have received pimavanserin solution have reported a strong bitter, acidic, or burning sensation in the mouth.² Ingestion of a high-fat meal had no significant effect on rate (C_{max}) and extent (AUC) of pimavanserin exposure when administered as a tablet formulation.^{1,3}

Effect of Crushing Pimavanserin Tablets

There are no data looking specifically at the PK parameters of crushed pimavanserin tablets; however, because pimavanserin is supplied as an immediate-release formulation,¹ no changes to PK parameters would be expected.

References

- 1. NUPLAZID[®] (pimavanserin) [package insert]. San Diego, CA. Acadia Pharmaceuticals Inc. [Link]
- 2. Vanover KE, Robbins-Weilert D, Wilbraham DG, Mant TG, van Kammen DP, Davis RE, Weiner DM. Pharmacokinetics, tolerability, and safety of ACP-103 following single or multiple oral dose administration in healthy volunteers. *J Clin Pharmacol.* 2007;47(6):704-714. [PubMed]
- 3. Vanover KE, Robbins-Weilert D, Wilbraham DG, Mant TG, van Kammen DP, Davis RE, Weiner DM. The effects of food on the pharmacokinetics of a formulated ACP-103 tablet in healthy volunteers. *J Clin Pharmacol.* 2007;47(7):915-919. [PubMed]