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

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NUPLAZID® (pimavanserin) Administration Through a Nasogastric Tube

This letter is being provided based on your specific request for information on the administration of pimavanserin through a nasogastric (NG) tube. There is currently no data specific to the administration of pimavanserin through other types of feeding tubes.

The following information on NG tube administration relates to the 34 mg capsule. The ability to administer aqueous dispersion of the pimavanserin 10 mg tablet through an NG tube has not been assessed.

There is currently no clinical data for the administration of pimavanserin through an NG tube.

Summary

- The ability to administer aqueous dispersion of the pimavanserin 34 mg capsule through an NG tube with acceptable recovery was demonstrated in an **NG tube compatibility study**.[1]
- The ability to deliver 34 mg of pimavanserin with >95% recovery within 24 hours at ambient room temperature after the contents were dispersed in water, with **acceptable stability**, was demonstrated *in vitro*.[2]
- The **bioavailability** of pimavanserin oral tablet and pimavanserin solution was found to be essentially identical.[3]

NG Tube Compatibility Study

The ability to administer an aqueous dispersion of pimavanserin 34 mg through an NG tube was assessed by dissolving the contents of one 34 mg capsule into water (40 mL). Three samples with pimavanserin were assayed against one control sample (water only) after being passed through an NG tube.[1]

The study demonstrated the ability to administer aqueous dispersion of the pimavanserin 34 mg capsule through an NG tube with acceptable recovery. The assay results between the control sample and mean results from the 3 pimavanserin samples exposed to NG tube matched within 2%.[1]

In Vitro Stability Study

The stability of pimavanserin was assessed by sprinkling the contents of one 34 mg capsule into a flask containing water (40 mL). Samples were tested at time 0, 2, 4, and 24 hours after storage at ambient conditions.[2]

This study demonstrated the ability to deliver 34 mg of pimavanserin with >95% recovery within 24 hours after the contents were dispersed in water. The stability of pimavanserin in water was acceptable over 24 hours at ambient room temperature.[2]

Pharmacokinetic Studies

The pharmacokinetics of pimavanserin administered as a solution by NG tube have been assessed in a Phase 1 study in healthy, young, male volunteers. The orally administered tablet and solution administered via NG tube were 99.7% bioequivalent.[4] The bioavailability of pimavanserin oral tablet and pimavanserin solution was found to be essentially identical.[3]

References

1. Acadia Pharmaceuticals Inc. Data on File. Report 18-090-00. 2019.
2. Bokser AD, Adegbenle YH, Stoisavljevic V, Norton JC. In Vitro Stability and Recovery Studies of Pimavanserin in Water and in Different Vehicles Orally Administered. *Drugs R D.* 2022;22(1):95-104. **[PubMed]**
3. NUPLAZID® (pimavanserin) [package insert]. San Diego, CA. Acadia Pharmaceuticals Inc. **[Link]**
4. Vanover KE, Robbins-Weilert D, Wilbraham DG, et al. 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]**