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GILEAD | Medical Information

Letairis® (ambrisentan) Crushing or Splitting of Tablets

This document is in response to your request for information regarding Letairis® (ambrisentan [ABS]) and the crushing or splitting of tablets.

Some data may be outside of the US FDA-approved prescribing information. In providing this data, Gilead Sciences, Inc. is not making any representation as to its clinical relevance or to the use of any Gilead product(s). For information about the approved conditions of use of any Gilead drug product, please consult the FDA-approved prescribing information.

The full indication, important safety information, and boxed warnings are available at: www.gilead.com/-/media/files/pdfs/medicines/cardiovascular/letairis/letairis_pi.

Product Labeling[1]

Do not split, crush, or chew tablets.

ABS is a carboxylic acid with a pKa of 4. ABS is practically insoluble in water and in aqueous solutions at low pH. Solubility increases in aqueous solutions at higher pH.

Available Data on Crushing or Splitting ABS Tablets

Gilead Data

ABS tablets are not enteric-coated and do not possess a sustained-release mechanism. However, the stability of ABS in liquids is unknown. Currently, there are no Gilead studies evaluating the safety, efficacy, and pharmacokinetic parameters of a split or crushed ABS tablet compared with a whole tablet.

Similarly, splitting ABS tablets has not been studied, and it is not recommended. There are no studies evaluating the pharmacokinetics of a split ABS tablet versus a whole tablet.

Non-Gilead Data

A literature search was conducted in Ovid MEDLINE and Embase databases for studies published up to January 15, 2026, using the search terms Letairis, ambrisentan, and cutting, crushing, splitting tablets, and related search terms. The following relevant citation was found:

- Cramer J, Bevry M, Handler S, Tillman K, Abourashed EA. Stability determination of an extemporaneously compounded ambrisentan suspension by high performance liquid chromatography analysis. *J Pediatr Pharmacol Ther.* 2021;26(3):265-270. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8021248/

Reference

1. Enclosed. Gilead Sciences Inc, LETAIRIS® (ambrisentan) tablets, for oral use. US Prescribing Information. Foster City, CA.

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Letairis US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/cardiovascular/letairis/letairis_pi.

Follow-Up

For any additional questions, please contact Gilead Medical Information at:

☎1-866-MEDI-GSI (1-866-633-4474) or 🖱 www.askgileadmedical.com

Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or
🖱 www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🖱 www.accessdata.fda.gov/scripts/medwatch

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