GILEAD | Medical Information

Zydelig® (idelalisib) Crushing or Splitting Tablets

This document is in response to your request for information regarding crushing or splitting Zydelig® (idelalisib) 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/oncology/zydelig/zydelig_pi.

Product Labeling[1]

Idelalisib tablets are for oral use, and the tablets should be swallowed whole. Idelalisib tablets may be taken with or without food.

Information related to crushing or splitting idelalisib tablets is not contained within the current product labeling. Therefore, the decision to administer idelalisib as a crushed tablet is at the discretion of the prescribing or dispensing health care professional.

Crushing or Splitting Idelalisib Tablets

Idelalisib is a white to off-white solid with a pH-dependent aqueous solubility ranging from <0.1 mg/mL at pH 5 to 7 to over 1 mg/mL at pH 2 under ambient conditions.[2]

Each 150 mg tablet of idelalisib contains 150 mg of idelalisib and the following inactive ingredients: microcrystalline cellulose, hydroxypropyl cellulose, croscarmellose sodium, sodium starch glycolate, and magnesium stearate. These tablets are film-coated with a material containing the following inactive ingredients: red iron oxide, polyethylene glycol, talc, polyvinyl alcohol, and titanium dioxide.[2]

Each 100 mg tablet contains 100 mg of idelalisib and the following inactive ingredients: microcrystalline cellulose, hydroxypropyl cellulose, croscarmellose sodium, sodium starch glycolate, and magnesium stearate. These tablets are film-coated with a material containing the following inactive ingredients: FD&C Yellow #6/Sunset Yellow FCF Aluminum Lake, polyethylene glycol, talc, polyvinyl alcohol, and titanium dioxide.[2]

Crushing idelalisib tablets into a liquid medium has not been studied and is not recommended. Currently, there are no studies evaluating the pharmacokinetics (eg, oral bioavailability) of a crushed idelalisib tablet dispersed into a liquid medium (eg, milk, water, juice) compared with a whole tablet.

Similarly, splitting idelalisib tablets has not been studied, and it is not recommended. Currently, there are no studies evaluating the pharmacokinetics of a split tablet vs a whole tablet. Therefore, the decision to administer idelalisib as a crushed or split tablet is at the discretion of the prescribing or dispensing health care professional.

References

1. Enclosed. Gilead Sciences Inc, ZYDELIG® (idelalisib) tablets, for oral use. US Prescribing Information. Foster City, CA.
2. Gilead Sciences Inc. Data on File.

Product Label

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