

ZYTIGA® (abiraterone acetate)

ZYTIGA - Crushing and Splitting Tablets

SUMMARY

- Janssen cannot recommend any practices, procedures, handling or dosage and administration techniques that deviate from the approved product labeling.
- ZYTIGA is not commercially available as a solution or suspension.
- Data from clinical studies including pharmacokinetic (PK) and pharmacodynamic studies of crushing or splitting ZYTIGA tablets for administration have not been published.
- A descriptive, observational, transverse study evaluated survey results from 950 patients regarding splitting or crushing medications. The purpose of the survey was to evaluate patient knowledge of oral medications that could or could not be crushed or split and to create a list of medications available in Mexico that should not be crushed or split. Mucosal irritation was noted as rationale for including ZYTIGA in a list of medications that should not be split or crushed.¹

CLINICAL DATA

No relevant clinical study information was identified for crushing or splitting tablets; however, **Marbury et al (2014)**² reported the results of single-dose administration studies investigating the impact of hepatic or renal impairment on abiraterone acetate PK and safety in noncancer patients compared with healthy controls (n=8 in each group). There were no details included in the publication regarding preparation of the suspension dosage form utilized in one of the studies. The studies did not evaluate multiple-dosing PK, safety, and efficacy in patients with prostate cancer.

LITERATURE SEARCH

A literature search of MEDLINE®, Embase®, BIOSIS Previews®, and Derwent Drug File (and/or other resources, including internal/external databases) was conducted on 15 November 2023.

REFERENCES

1. Gracia-Vasquez SL, Gonzalez-Barranci P, Camacho-Mora IA, et al. Medications that should not be crushed. *Medicina Universitaria*. 2017;19(75):50-63.

2. Marbury T, Lawitz E, Stonerock R, et al. Single-dose pharmacokinetic studies of abiraterone acetate in men with hepatic or renal impairment. *J Clin Pharmacol*. 2014;54(7):732-741.