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Antineoplastic agents.

1 Carlson PA.
Cite Crit Care Nurs Q. 1996 Feb;18(4):1-15. doi: 10.1097/00002727-199602000-00002. PMID: 8689448 Review.
Share Advances in the field of oncology have led to the development of many **antineoplastic agents** for the treatment of cancer. Combination with other **agents** and modalities, along with dose intensification, has resulted in more toxicities, often requiring careful ma ...

Antineoplastic compounds in the environment-substances of special concern.

2 Kümmerer K, Haiß A, Schuster A, Hein A, Ebert I.
Cite Environ Sci Pollut Res Int. 2016 Aug;23(15):14791-804. doi: 10.1007/s11356-014-3902-8. Epub 2014 Dec 6.
Share PMID: 25475615
In a balance, we identified a total of 102 active pharmaceutical ingredients of the ATC-group L01 (**antineoplastic agents**), which are environmentally relevant. In Germany, 20.7 t of **antineoplastic agents** was consumed in 2012. The share of drugs with DNA ...

Dacarbazine.

3 Al-Badr AA, Alodhaib MM.
Cite Profiles Drug Subst Excip Relat Methodol. 2016;41:323-77. doi: 10.1016/bs.podrm.2015.12.002. Epub 2016 Jan 25.
Share PMID: 26940170 Review.
Dacarbazine is a cell cycle nonspecific **antineoplastic** alkylating agent used in the treatment of metastatic malignant melanoma. ...

Preface.

4 Uchegbu IF.
Cite Pharm Nanotechnol. 2017;5(1):2. doi: 10.2174/221173850501170316193147. PMID: 28948906 No abstract available.
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To Take or Not to Take With Meals? Unraveling Issues Related to Food Effects Labeling for Oral Antineoplastic Drugs

Jiexin Deng¹, Satjit S Brar², Lawrence J Lesko¹

Affiliations + expand **4b**
PMID: 29197167 DOI: 10.1002/cpdd.416

Abstract

There has been controversy regarding whether bioavailability of certain oral oncology drugs should be maximized by taking these medications with food, irrespective of label instructions in the dosing and administration section. To provide insight into this controversy, we conducted an in-depth analysis for oral antineoplastic drugs approved by the Food and Drug Administration in 2000-2016 and identified important issues influencing food labeling decisions. Furthermore, a case study involving sonidegib, a drug approved for locally advanced basal cell carcinoma with a significant food effect on exposure, was used to demonstrate the consequences of failure to adhere to food label recommendations using drug-specific population pharmacokinetic and exposure-toxicity models. In 2000-2009, 80% (4 out of 5) of all approved oral antineoplastics with increased bioavailability in the fed state were labeled as "take on empty stomach." In contrast, we found that in 2010-2016 there is a greater diversity in food recommendations for drugs with increased bioavailability in the fed state. Currently, many oral oncology drugs are given with food to maximize their bioavailability; however, as seen from our case study of sonidegib, failure to fully adhere to label recommendations to either take with food or not could lead to adverse consequences in terms of safety and efficacy.

Keywords: adverse effects; antineoplastics; bioavailability; food effects; label recommendations.

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Fasted	6	13.7%
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To Take or Not to Take With Meals? Unraveling Issues Related to Food Effects Labeling for Oral Antineoplastic Drugs

Jixin Deng¹, Satjit S. Brar², and Lawrence J. Lesko¹

Abstract
There has been controversy regarding whether bioavailability of certain oral oncology drugs should be maximized by taking these medications with food, irrespective of label instructions in the dosing and administration section. To provide insight into this controversy, we conducted an in-depth analysis for oral antineoplastic drugs approved by the Food and Drug Administration in 2000-2016 and identified important issues influencing food labeling decisions. Furthermore, a case study involving sonidegib, a drug approved for locally advanced basal cell carcinoma with a significant food effect on exposure, was used to demonstrate the consequences of failure to adhere to food label recommendations using drug-specific population pharmacokinetic and exposure-toxicity models. In 2000-2009, 80% (4 out of 5) of all approved oral antineoplastics with increased bioavailability in the fed state were labeled as "take on empty stomach." In contrast, we found that in 2010-2016 there is a greater diversity in food recommendations for drugs with increased bioavailability in the fed state. Currently, many oral oncology drugs are given with food to maximize their bioavailability; however, as seen from our case study of sonidegib, failure to fully adhere to label recommendations to either take with food or not could lead to adverse consequences in terms of safety and efficacy.

Keywords
food effects, antineoplastics, bioavailability, adverse effects, label recommendations

The development of oral antineoplastic drug therapy has gained tremendous traction in recent years as the proportion of oral anticancer agents has greatly increased compared to nonoral routes of administration. Oral formulations have the potential to greatly improve the overall quality of life and compliance/adherence because the majority of patients prefer oral instead of parenteral formulations for convenience and the ability to receive treatment at home among other positive attributes.¹ On the other hand, because most oral antineoplastics require daily oral administration for expected therapeutic benefit, greater responsibility is placed on prescribers and patients for taking medications according to drug labels that are based on evidence from drug development. Not following labeled dosing recommendations is a major concern to oncologists, considering that these are potent agents with narrow therapeutic indices intended for treating serious conditions.²

drugs are taken with meals (i.e., taking the drug within 1 hour before or 2 hours after a meal) vs in a fasting state. Because food effects on bioavailability (BA) could affect the safety and efficacy of drug therapy, the Food and Drug Administration (FDA) recommends food-effect BA studies be conducted early in the drug development process to guide and select formulations and their directions for use in late-phase clinical trials. In general, the FDA Guidance on Food Effects recommends that the highest strength of the to-be-marketed drug product should be tested in healthy volunteers

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ARTICLE
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