

Indinavir (*Crixivan*)

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Drug Summary

Indinavir, a protease inhibitor, is no longer used as part of antiretroviral therapy because of toxicity concerns. Indinavir was FDA-approved in 1996 and, in combination with two nucleoside reverse transcriptase inhibitors (NRTIs), played a major role in the early years of highly active antiretroviral therapy. Subsequently, more tolerable and safer agents with more convenient dosing schedules replaced indinavir. A major limitation of indinavir is that it frequently causes kidney stones; thus, individuals taking indinavir are advised to drink at least 1.5 liters of water per day to prevent nephrolithiasis. It also requires more frequent dosing than currently recommended agents, has strict food requirements, and has been associated with cosmetically disturbing lipoaccumulation. Indinavir is no longer recommended as a component of any antiretroviral therapy regimen and patients taking indinavir should switch to a safer and currently recommended antiretroviral agent.

Key Clinical Trials

Early studies of indinavir primarily focused on the combination of indinavir with two NRTIs (usually zidovudine plus lamivudine) as treatment for individuals with a history of zidovudine monotherapy. For example, investigators enrolled patients with a CD4 count less than 200 cells/mm³ and at least 6 weeks of prior zidovudine therapy; triple therapy with indinavir plus zidovudine plus lamivudine was more effective in slowing the progression of HIV disease than dual therapy with zidovudine plus lamivudine [ACTG 320]. In a similar trial that enrolled patients with at least 6 months of prior zidovudine treatment and a CD4 count less than 50 cells/mm³, the three-drug regimen of indinavir plus zidovudine plus lamivudine demonstrated significantly higher rates of HIV RNA decrease to below 500 copies/mL and significantly better improvements in CD4 cell count than indinavir monotherapy or zidovudine plus lamivudine dual therapy [039]. Subsequently, in a trial that enrolled individuals not previously treated with lamivudine, non-nucleoside reverse transcriptase inhibitors, or protease inhibitors, the three-drug combination of efavirenz plus zidovudine plus lamivudine led to higher rates of viral suppression rates and better tolerability as compared to indinavir plus zidovudine plus lamivudine [006]. Investigators explored the use of dual or mono maintenance therapy and found patients on triple therapy with indinavir plus zidovudine plus lamivudine and

HIV RNA levels less than 200 copies/mL had greater virologic failure when switched to a maintenance regimen of indinavir alone or zidovudine plus lamivudine [[ACTG 343](#)].

Adverse Effects

Indinavir crystallizes in the urinary tract and causes kidney stones; thus individuals taking indinavir are advised to drink at least 1.5 liters of water per day to prevent nephrolithiasis. In addition, indinavir commonly causes gastrointestinal side effects, including stomach upset, nausea, and diarrhea. Indinavir may raise serum lipid parameters and blood glucose. It can also cause unconjugated (indirect) hyperbilirubinemia.

Use In Pregnancy

In the HHS Perinatal Guidelines section Recommendations for Use of Antiretroviral Drugs During Pregnancy (last updated October 19, 2017), ritonavir-boosted **indinavir** is designated as Not Recommended for Initial ART in Pregnancy; reasons cited for this recommendation in the Perinatal Guidelines include concerns for nephrolithiasis and maternal hyperbilirubinemia.

- For additional information regarding the safety and toxicity of indinavir in pregnancy see the HHS Perinatal Guidelines summary on [Indinavir](#).
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Resistance

For a listing of the most common clinically significant mutations associated with indinavir (IDV) resistance, see the [PI Resistance Notes on the Stanford University HIV Drug Resistance Database](#).

Key Drug Interactions

For complete information on indinavir-related drug interactions, see the [Drug Interactions section in the Indinavir \(Crixivan\) Prescribing Information](#).

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PDF created May 29, 2020, 7:46 am

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<https://www.hiv.uw.edu/page/treatment/drugs/indinavir>