

## Kaletra® (Iopinavir/ritonavir) – Updated Contraindications/Drug Interactions

- On November 22, 2016, the <u>FDA approved</u> new updates to the *Contraindications* and *Drug Interactions* sections of the drug label for <u>Kaletra (lopinavir/ritonavir)</u> pertaining to the addition of new drugs.
- Kaletra is indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults and pediatric patients (14 days and older).
- The following points should be considered when initiating therapy with Kaletra:
  - The use of other active agents with Kaletra is associated with a greater likelihood of treatment response.
  - Genotypic or phenotypic testing and/or treatment history should guide the use of Kaletra. The number of baseline lopinavir resistance-associated substitutions affects the virologic response to Kaletra.
- The *Contraindications* section has been updated to include the following drugs: Multaq® (dronedarone), colchicine, and Zepatier™ (elbasvir/grazoprevir).
- Administration of Kaletra and Multaq may cause cardiac arrhythmias. Administration of Kaletra and colchicine has the potential for serious and/or life-threatening reactions in patients with renal and/or hepatic impairment. Administration of Kaletra with Zepatier has the potential for increased risk of alanine transaminase elevations.
- The *Drug Interactions* section has been updated to include information about lopinavir being an organic anion-transporting polypeptide (OATP)1B1 inhibitor; addition of <u>Cresemba® (isavuconazonium sulfate)</u>, colchicine, and <u>Viekira Pak™ (ombitasvir/paritaprevir/ritonavir and dasabuvir)</u> to the list of established and other potentially significant drug interactions; and addition of <u>Intelence® (etravirine)</u> and <u>Edurant®</u> (rilpivirine) to the list of drugs with no observed or predicted interactions with Kaletra.
- The co-administration of Kaletra and Cresemba causes an increase in the concentration of Cresemba. The two agents should be co-administered with caution. Alternative antifungal therapies should be considered in these patients.
- The co-administration of Kaletra and colchicine causes an increase in the concentration of colchicine. Consult package label for dosing recommendations for colchicine for patients who do not have renal and/or hepatic impairment.
- The co-administration of Kaletra and Viekira Pak causes increases in ombitasvir, paritaprevir and ritonavir concentrations. It is not recommended to co-administer Kaletra and Viekira Pak.
- Drug interaction or clinical studies reveal no clinically significant interaction between Kaletra and Intelence or Edurant.
- The Medication Guide section has also been updated with similar information.



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