



Pharmacokinetics Clinical Report of Kaletra Drug in HIV Infected Patients

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DESCRIPTION

HIV (Human Immunodeficiency Virus) is a virus that attacks the body's immune system. If left untreated, HIV can lead to AIDS (Acquired Immune Deficiency Syndrome). With good medical care, HIV can be controlled. People living with HIV can receive effective HIV treatment and healthier and longer lives with proper medical treatment. People who take HIV treatment as prescribed will not progress to another stage (such as AIDS). Kaletra is a prescription drug used in combination with other antiretroviral drugs to treat Human Immunodeficiency Virus-1 (HIV-1) infection in adults and children 14 days and older. Kaletra (lopinavir/ritonavir) is a combination of two antiviral drugs called protease inhibitors used to treat HIV. This product is used with other HIV medications to control HIV infection. It reduces the amount of HIV in the body and makes the immune system work better. This reduces the chance of HIV complications (new infections, cancer, etc.) and improves the quality of life. Both lopinavir and ritonavir belong to a class of drugs known as HIV protease inhibitors. Ritonavir increases ("boosts") lopinavir levels. This increases the effectiveness of lopinavir. To reduce the risk of passing HIV infection to others, continue to take all HIV medications as directed by the doctor. During sexual activity, use an effective barrier method (latex or polyurethane condoms/dental dams) as directed by the doctor.

Do not share personal items (needles/syringes, toothbrushes, razors, etc.) that may have come in contact with blood or other bodily fluids. Kaletra should only be used during pregnancy if prescribed. Kaletra can be used with fluticasone, rifabutin, itraconazole, ketoconazole, antidepressants, blood thinners, calcium channel blockers, cholesterol-lowering drugs, drugs that lower the immune system, heart arrhythmia drugs, other HIV/AIDS drugs, insulin or oral diabetes. Many other medicines may interact with Kaletra. Kaletra oral solution contains approximately 42% (v/v) ethanol and approximately 15% (w/v) propylene glycol.

Kaletra is effective in reducing HIV in most adults and children after 14 days of age. The drug is well tolerated and side effects are

easy to manage. The most common side effects of Kaletra in adults are upper respiratory tract infections (colds), nausea (feeling sick), and diarrhea. Kaletra is taken by patients with severe liver disease, St. John's wort (an herbal preparation used to treat depression), or drugs that break down in the same way as Kaletra and are harmful in high blood levels.

The recommended dose of Kaletra Tablets is 400/100 mg twice daily (administered as two 200/50 mg tablets). The recommended dose of Kaletra oral solution is 400/100 mg (5 ml) twice daily. In adult patients, Kaletra tablets 800/200 mg (four 200/50 mg tablets) once daily, with or without taking food and should be administered once daily for patient management.

The use of once-daily dosing is associated with few Protease Inhibitors (PI)-associated mutations (i.e., fewer than 3 PI mutations based on clinical trial results) should be restricted to adult patients and the risk of less durable virologic suppression and increased risk of diarrhea compared to the standard twice-daily recommended dose. Oral solutions are available for patients with dysphagia. An approximately 30% increase in lopinavir exposure has been observed in HIV-infected patients with mild to moderate hepatic impairment but is not expected to be clinically relevant.

About 79% (259/326) of patients taking Kaletra compared with 71% (233/327) of patients taking nelfinavir in previously untreated adults for HIV at 24 weeks after 16 weeks. Among children aged 14 days, between 71% and 85% of patients received 48 weeks of treatment with Kaletra. After that, the virus level became very low.

Take this medicine by mouth, usually 1 to 2 times daily, with or without food, as directed by the doctor. Swallow the pill completely. Do not crush, break or chew tablets.

Dosage is based on the patient's medical condition, response to treatment, and other medications that are taken by a patient. For children, the dosage also depends on age, weight, and height. Once-daily use of this medication is not recommended for children under the age of 18.

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