

Abbott and Brazil Reach Agreement. No Patent Will Be Broken.

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Abbott announced today that it achieved its goals in negotiating an agreement with the government of Brazil regarding Kaletra (lopinavir/ritonavir), the leading protease inhibitor used as an AIDS treatment.

According to the American laboratory, the agreement accomplishes Abbott's objectives of helping Brazil expand patient access to Kaletra while preserving the company's intellectual property rights, which Abbott was not willing to negotiate.

The agreement does not specify a per-capsule price, and will not be at the low price quoted for local and generic manufacturers. The price of Kaletra will be dependent on the number of patients treated.

Abbott agreed to provide assistance to Brazil to enable local manufacture of Kaletra for HIV/AIDS patients in Brazil once the patent expires in 2015. Terms of this portion of the agreement are under discussion.

Abbott said in a statement: "It is strong intellectual property protection that has enabled the discovery and development of the many HIV treatments available for patients today, and also ensures future advances to address a virus that continues to mutate and elude a cure.

"Abbott is committed to protecting its intellectual property so that innovation flourishes for the benefit of patients around the world."

Safety Information

Kaletra is always used in combination with other anti-HIV medicines to treat people with human immunodeficiency virus (HIV) infection.

Kaletra should not be taken by patients who have had an allergic reaction to Kaletra or any of its ingredients, including lopinavir or ritonavir.

Taking certain medications with Kaletra could create the potential for serious side effects that could be life threatening.

Kaletra should not be taken with astemizole, cisapride, dihydroergotamine, ergonovine, ergotamine, methylergonovine, midazolam, pimozide, terfenadine or triazolam.

In addition, Kaletra should not be taken with fluticasone propionate, rifampin, simvastatin, or products containing St. John's Wort (*Hypericum perforatum*).

Particular caution should be used when taking Kaletra with sildenafil, tadalafil, or vardenafil. Pancreatitis and liver problems, which can be fatal, have been reported.

Patients should tell their doctor if they have had liver disease such as hepatitis. In patients taking protease inhibitors, increased bleeding (in patients with hemophilia) and diabetes/high blood sugar have occurred.

Changes in body fat have been seen in some patients receiving antiretroviral therapy. Some patients receiving Kaletra have had large increases in triglycerides and cholesterol. Varying degrees of cross-resistance among protease inhibitors have been observed.

In Kaletra clinical trials, the most commonly reported side effects of moderate-to-severe intensity were abdominal pain, abnormal bowel movements, diarrhea, feeling weak or tired, headache, nausea and vomiting.

Children taking Kaletra may sometimes get a skin rash. This is not a complete list of reported side effects. Kaletra oral solution contains alcohol.

Kaletra does not cure HIV infection or AIDS and does not reduce the risk of passing HIV to others.

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs more than 60,000 people and markets its products in more than 130 countries.

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