Aptivus

Generic Name: tipranavir

Pronunciation: AP-tih-vus

Abbreviation: TPV

Drug Class: Protease Inhibitors (PIs)

Company: Boehringer Ingelheim

Approval Status: Approved

Generic Version Available: No

Drug Indication

Not part of a recommended or alternative treatment regimen for antiretroviral-naive people living with HIV, according to the U.S. Department of Health and Human Services (DHHS) Panel on Antiretroviral Guidelines for Adults and Adolescents. Generally reserved for treatment-experienced people living with HIV. Visit http://aidsinfo.nih.gov/contentfiles/lvguidelines/aa_recommendations.pdf for the full DHHS guidelines.

General Info

Aptivus is an HIV medication. It is in a category of HIV medicines called protease inhibitors. Aptivus was approved by the U.S. Food and Drug Administration for use by people living with HIV in June 2005.

Aptivus is only approved for HIV-infected people who have tried and failed HIV drug regimens (including those containing protease inhibitors) in the past. It is not approved for HIV-infected people starting HIV treatment, or a protease inhibitor, for the first time (unless they were infected with a strain of HIV resistant to multiple protease inhibitors).

Aptivus must be used in combined with Norvir (ritonavir) and other HIV drugs.

Dosage

Adult Dose: Two 250mg capsules plus two 100mg Norvir tablets (or capsules), twice a day.

Pediatric Dose: Age 2 to 18 years: dosing is based on body weight or body surface area and should not exceed the adult daily dose.

Dosing Info: Aptivus and Norvir should be taken with food, preferably a meal. Aptivus/Norvir should not be taken with other protease inhibitors. If taken with Videx or Videx EC (didanosine), Aptivus/Norvir should be taken at least two hours before or two hours after taking ddI.

Side Effects

The most common short-term side effects noticed in clinical trials involving HIV-positive people taking Norvir-boosted Aptivus were: nausea, vomiting, diarrhea, stomach pain, tiredness, and headache.

Norvir-boosted Aptivus may increase the risk of intracranial hemorrhage (ICH)—bleeding in the brain due to ruptured blood vessels in the head—that can lead to stroke or death.

Norvir-boosted Aptivus has been associated with reports of hepatitis and significant liver toxicity (hepatic decompensation), including some fatal cases. Extra caution is recommended for HIV-positive patients with hepatitis B or hepatitis C, who are at the highest risk of liver-related side effects. Norvir-boosted Aptivus is not recommended for people with moderate to severe liver impairment (Child-Pugh Class B or C).

Aptivus, a sulfa-containing drug, should be used with caution in patients with a known sulfa allergy. Mild to moderate rashes and increased sensitivity to the sun (photosensitivity) have been reported in HIV-positive people taking Norvir-boosted Aptivus. Women taking Norvir-boosted Aptivus with medications that contain estrogen have an increased risk of developing a rash.

Some people may experience increases in their lipid levels (triglycerides and cholesterol) or diabetes risk while being treated with protease inhibitors, including Norvir.

Drug Interactions

Norvir-boosted Aptivus can increase or decrease the levels of many other drugs in the body, potentially increasing the risk of serious side effects or decreasing the effectiveness of treatment (some coadministered drugs can also decrease or increase Crixivan levels in the bloodstream). There are several prescription and over-the-count drugs and supplements that should not be taken with Norvir-boosted Aptivus. Combining Norvir-boosted Aptivus with some medications

may also require dose adjustments to accommodate for drug-drug interactions. Consult the Aptivus package insert for more details: http://bidocs.boehringer-ingelheim.com/BIWebAccess/ViewServlet.ser?docBase=renetnt&folderPath=/Prescribing+Information/PIs/Aptivus/Aptivus.pdf

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Other Info

Before taking this medication, tell your doctor if you have kidney disease, liver disease (including hepatitis B), or have risk factors for excessive bleeding from trauma, surgery or other medications conditions, or if you are receiving medications known to increase the risk of bleeding (e.g., anticoagulants or antiplatelets used to prevent or treat heart attacks). In addition, tell your doctor if you are pregnant or planning to become pregnant, or if you are breastfeeding.

It is also very important that your health care provider and pharmacist know all prescription and over-the-counter medications and supplements you are taking at all times while using an HIV treatment regimen that contains Aptivus.

For More Info: http://bidocs.boehringer-ingelheim.com/BIWebAccess/ViewServlet.ser?docBase=renetnt&folderPath=/Prescribing+Information/PIs/Aptivus/Aptivus.pdf

Co-Pay Program Info: https://www.poz.com/basics/hiv-basics/drug-assistance-programs

Patient Assistance Program Info: https://www.poz.com/basics/hiv-basics/drug-assistance-programs

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