



fact sheet

APTIVUS capsules/oral solution

What is APTIVUS?

APTIVUS is a medicine called a protease inhibitor (PI) that is used to treat adults with Human Immunodeficiency Virus (HIV). APTIVUS blocks HIV protease, an enzyme which is needed for HIV to make more virus. When used with other anti-HIV medicines, APTIVUS may reduce the amount of HIV in your blood and increase the number of CD4 cells. Reducing the amount of HIV in the blood may keep your immune system healthy, so it can help fight infections.

APTIVUS is always taken with NORVIR® (ritonavir) and at the same time as NORVIR. When you take APTIVUS with NORVIR, you must always use at least two other anti-HIV medicines as part of combination therapy. The use of other active agents with APTIVUS is associated with a greater likelihood of treatment response.

See page 2 or click here for [Important Safety Information for APTIVUS](#).

APTIVUS does not cure HIV, and an undetectable viral load does not mean you are cured of HIV. It is still possible to pass the virus on to others. Be sure to practice safer sex and minimize other risky behaviors.

Who can take APTIVUS?

APTIVUS/ritonavir (APTIVUS/r) is indicated for use in HIV infected patients who are treatment-experienced and infected with HIV strains resistant to more than one PI. APTIVUS must be co-administered with ritonavir to boost the therapeutic levels of APTIVUS; otherwise, levels of APTIVUS will be insufficient to inhibit HIV replication. APTIVUS/r must be used in combination with at least two other anti-HIV medicines.

APTIVUS is not for patients who have never taken HIV treatment. APTIVUS should not be used in children under 2 years of age.

What is the recommended dosage for APTIVUS?

The approved adult dose of APTIVUS is 500 mg taken with 200 mg of ritonavir, twice daily.

The recommended pediatric dose of APTIVUS for both capsules and oral solution is 14 mg/kg with 6 mg/kg ritonavir, or 375 mg/m² co-administered with ritonavir 150 mg/m², taken twice daily, and not to exceed a maximum dose of APTIVUS 500 mg co-administered with ritonavir 200 mg twice daily.

APTIVUS must be co-administered with ritonavir to boost the therapeutic levels of APTIVUS; otherwise, levels of APTIVUS will be insufficient to inhibit HIV replication. APTIVUS/r must be used in combination with at least two other anti-HIV medicines.

What is the most important safety information about APTIVUS?

Important Safety Information for APTIVUS

APTIVUS capsules are always taken with Norvir® (ritonavir). This is referred to as APTIVUS/r.

Patients taking APTIVUS, together with Norvir® (ritonavir), may develop severe liver disease that can cause death. If you develop any of the following symptoms of liver problems, you should stop taking APTIVUS and Norvir® (ritonavir) and call your healthcare professional right away: tiredness, general ill feeling or “flu-like” symptoms, loss of appetite, nausea (feeling sick to your stomach), yellowing of your skin or whites of your eyes, dark (tea-colored) urine, pale stools (bowel movements), or pain, ache, or sensitivity on your right side below your ribs. If you have chronic hepatitis B or C infection, your healthcare professional should check your blood tests more often because you have an increased chance of developing liver problems.

Patients taking APTIVUS together with Norvir® (ritonavir) may develop bleeding in the brain that can cause death. You should report any unusual or unexplained bleeding to your healthcare professional if you are taking APTIVUS together with Norvir® (ritonavir).

Indication

APTIVUS/r is indicated for use in HIV infected patients who are treatment-experienced and infected with HIV strains resistant to more than one protease inhibitor (PI). APTIVUS/r must be used in combination with at least 2 other anti-HIV medicines.

This indication is based on the results of the viral load levels in 2 controlled studies of APTIVUS/r during 48 weeks in treatment experienced adult patients. Both studies' patients had advanced HIV infection and had used 3 classes of anti-HIV medicines (NRTIs, NNRTIs, PIs). These patients also had ongoing HIV replication despite taking anti-HIV therapy.

Important information about APTIVUS

Patients taking APTIVUS may develop severe liver disease that can cause death. If you develop any of the following symptoms of liver problems, you should stop taking APTIVUS treatment and CALL your HCP right away: tiredness, general ill feeling or “flu-like” symptoms, loss of appetite, nausea (feeling sick to your stomach), yellowing of your skin or whites of your eyes, dark (tea-colored) urine, pale stools (bowel movements), or pain, ache, or sensitivity on your right side below your ribs. If you have chronic hepatitis B or C infection, your HCP should check your blood tests more often because you have an increased chance of developing liver problems.

Patients taking APTIVUS may develop severe bleeding in the brain that can cause death. You should report any unusual or unexplained bleeding to your HCP if you are taking APTIVUS.

- Your HCP will prescribe at least 2 other anti-HIV medicines with APTIVUS. This usually will increase the likelihood of treatment response.
- Baseline HIV resistance may affect your response to APTIVUS. Therefore, your HCP should conduct resistance tests and know your treatment history before prescribing APTIVUS.

For Patients

What is the most important safety information about APTIVUS? (continued)

- Tell your HCP if you have liver disease, are infected with hepatitis B or C infection, or reduced liver function because you may have increased chance of liver disease problems while taking APTIVUS.
- Your HCP should perform certain liver tests before you start therapy with APTIVUS. Your HCP will monitor the function of your liver during your APTIVUS therapy.
- Taking APTIVUS with certain drugs can reduce the effectiveness of your treatment and can result in serious or life-threatening events.
- Tell your HCP if you have hemophilia or other medical conditions that increase the chances of bleeding. Tell your HCP about medicines you are taking to find out if they may increase your chance of bleeding.
- If you are taking APTIVUS oral solution, which contains vitamin E, you should not take additional vitamin E other than that contained in a standard multivitamin.
- Tell your HCP immediately if you develop or if you suspect you have a skin rash. APTIVUS should be used with caution in patients with a known sulfa allergy.
- Patients may develop new or worsening diabetes, high blood sugar (hyperglycemia), immune reconstitution syndrome, changes in body fat, and elevated lipids. Your HCP may monitor your cholesterol and triglycerides before starting APTIVUS and while on treatment.
- Women taking APTIVUS and estrogen-based hormonal contraceptives are advised to use alternative methods of contraception during therapy with APTIVUS. Women using estrogens for birth control or hormone replacement have an increased chance of developing a skin rash while taking APTIVUS. If a rash occurs, it is usually mild to moderate, but you should call your HCP.
- Tell your HCP if you are thinking about becoming pregnant, if you are pregnant, or are thinking about breast-feeding. Breastfeeding can result in passing the HIV virus to your baby.
- The most common side effects of APTIVUS include diarrhea, nausea, fever, vomiting, tiredness, headache, and stomach pain. Rash was seen more frequently in children.
- APTIVUS should not be used in children under 2 years of age.

Please consult the [Full Prescribing Information](#) as well as the [Patient Package Insert \(PPI\)](#) including boxed WARNINGS, and [Important Safety Information](#) for *APTIVUS*.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

How long has APTIVUS been available in the U.S.?

APTIVUS/r received accelerated approval for use in the United States by the Food and Drug Administration in June 2005. Accelerated approval is a regulatory process that speeds the approval of therapies for serious or life-threatening illnesses that provide meaningful benefit to patients over existing treatments. APTIVUS/r was granted full (traditional) approval in the United States in October 2007 and was approved for pediatric patients in June 2008.

For additional information

APTIVUS is distributed by Boehringer Ingelheim Pharmaceuticals Inc. For additional information, please contact Susan Holz, Public Affairs & Communications at, susan.holz@boehringer-ingelheim.com or visit www.aptivus.us.