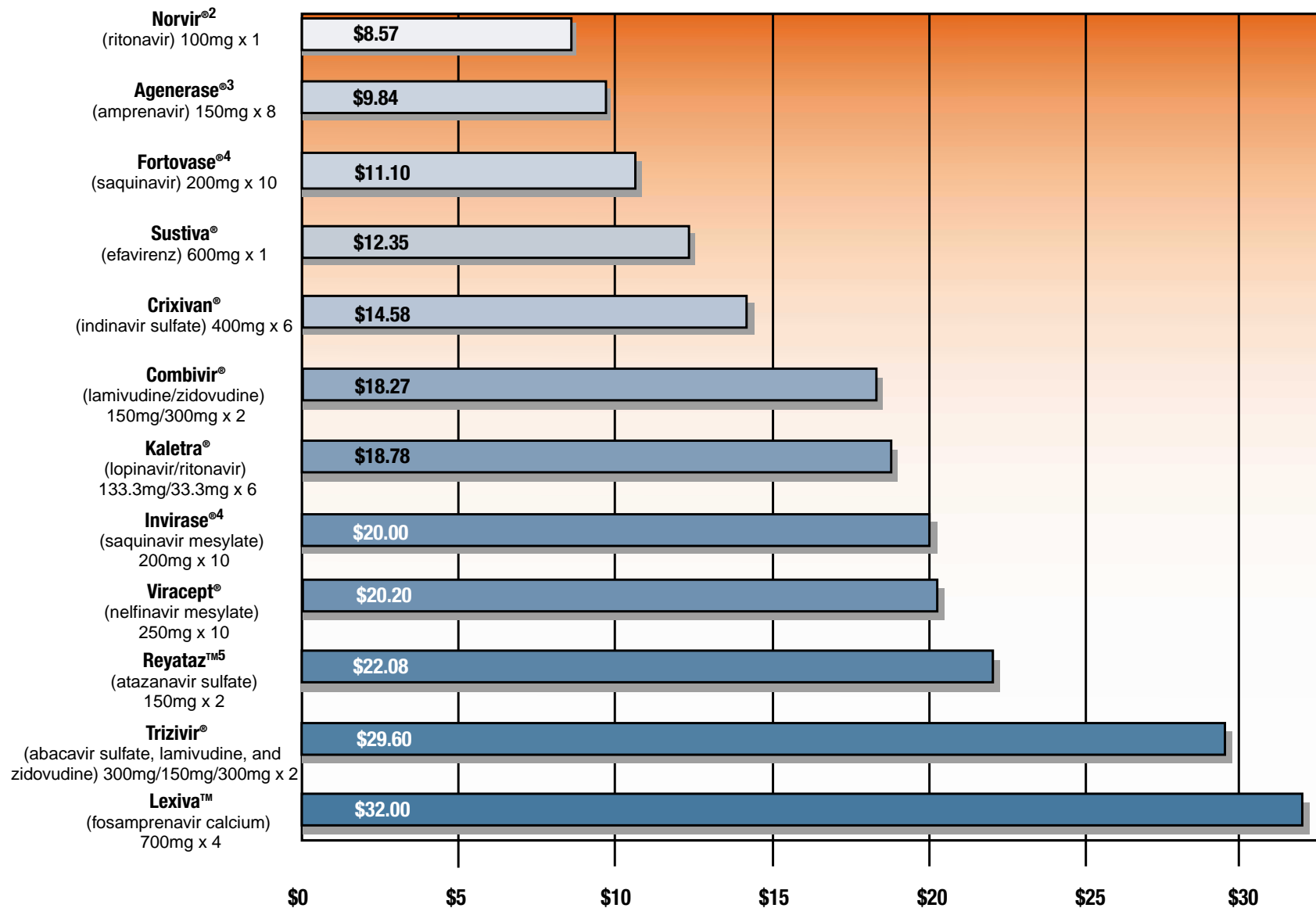


# Daily Cost of Common ARV Agents<sup>1</sup>



<sup>1</sup>Based on wholesale acquisition cost (WAC), Price Probe, access date, January 8, 2004. WAC may not represent actual price paid by pharmacies or consumers. Price comparisons do not imply comparable effectiveness of products. Dosages reflect commonly prescribed milligrams per day.

<sup>2</sup>Reyataz package insert.

<sup>3</sup>Verispan LLC, HIV Therapy Audit, Q3 2003.

<sup>4</sup>www.fda.gov; December 24, 2003.

<sup>5</sup>IMS Health, Weekly NPA Plus 7 Audit, December 26, 2003.

<sup>6</sup>Kaletra package insert.

<sup>7</sup>Norvir package insert.

Please see accompanying full Prescribing Information for Norvir and Kaletra.

The brands listed are trademarks of their respective owners.

Please reference the Prescribing Information for these products for complete dosing instructions.

## **Kaletra® (lopinavir/ritonavir) Indication and Safety Information®**

KALETRA is indicated in combination with other antiretroviral agents for the treatment of HIV infection. This indication is based on analyses of plasma HIV RNA levels and CD<sub>4</sub> cell counts in controlled studies of KALETRA of 48 weeks duration and in smaller, uncontrolled dose-ranging studies of KALETRA of 72 weeks duration.

KALETRA should not be given to patients who have had an allergic reaction to KALETRA (lopinavir/ritonavir) or any of its ingredients. KALETRA is contraindicated with astemizole, cisapride, dicyclanide, ergonovine, ergotamine, fentanyl, flecainide, flunitrazepam, methylergonovine, midazolam, piroxicam, propafenone, terfenadine or triazolam. KALETRA should not be co-administered with lovastatin, simvastatin, St. John's wort (*Hypericum perforatum*) or rifampin.

Concomitant use with sildenafil is expected to substantially increase sildenafil concentrations and may increase sildenafil-associated adverse events, including hypotension, syncope, visual changes, and prolonged erection.

Pancreatitis, including some fatalities, has been observed in patients receiving KALETRA.

Caution should be exercised when administering KALETRA to patients with hepatic impairment including those with hepatitis B or C or marked elevations in transaminases. There have been reports of hepatic dysfunction, including some fatalities. A causal relationship with KALETRA therapy has not been established. Increased AST/ALT monitoring should be considered in these patients, especially during the first several months of KALETRA treatment.

Treatment with KALETRA has resulted in large increases in total cholesterol and triglycerides, which should be monitored before and during therapy.

In patients receiving PIs, increased bleeding (in patients with hemophilia), new onset or exacerbation of diabetes mellitus, and hyperglycemia have been reported.

Various degrees of cross-resistance among protease inhibitors have been observed.

Redistribution and accumulation of body fat has been reported in patients receiving ARV therapy. A causal relationship has not been established.

In KALETRA clinical trials, the most common adverse events of moderate to severe intensity reported in  $\geq 2\%$  of patients were abdominal pain, asthenia, diarrhea, headache, nausea, and vomiting.

## **Norvir® (ritonavir) Indication and Safety Information<sup>7</sup>**

NORVIR is indicated in combination with other antiretroviral agents for the treatment of HIV infection. This indication is based on the results from a study in patients with advanced HIV disease that showed a reduction in both mortality and AIDS-defining clinical events for patients who received NORVIR either alone or in combination with nucleoside analogues. Median duration of follow-up in this study was 13.5 months.

NORVIR may not be right for everyone, including people with liver disease, hepatitis, or hemophilia.

Redistribution/accumulation of body fat has been observed in patients receiving protease inhibitors.

Elevated blood sugar levels have been reported in patients taking protease inhibitors.

Allergic reactions ranging from mild to severe have been reported.

Pancreatitis has been observed in patients receiving NORVIR therapy, including those who developed high triglycerides.

The risk of muscle pain, including severe muscle disease, may be increased when NORVIR is used in combination with HMG-CoA reductase inhibitors (statin class of lipid-lowering drugs).

Concomitant use of NORVIR with St. John's wort (*Hypericum perforatum*) is not recommended. St. John's wort may reduce NORVIR levels, lead to increased viral load and possible resistance to protease inhibitors.


Common adverse reactions include diarrhea, vomiting, asthenia, taste perversion, abdominal pain, anorexia, headache, peripheral paresthesia, circumoral paresthesia, and dizziness.

Coadministration of NORVIR with certain non-sedating antihistamines, sedative hypnotics, antiarrhythmics, or ergot alkaloid preparations may result in potentially serious and/or life-threatening adverse events.

NORVIR is contraindicated with the drugs listed below:

amiodarone	dihydroergotamine	midazolam	quinidine
astemizole	ergotamine	pimozide	terfenadine
bepridil	flecainide	propafenone	triazolam
cisapride			

**Please see accompanying full Prescribing Information for Norvir and Kaletra.**

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Abbott Park, IL 60064

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