



February 4, 2004

Dear HIV Care Provider:

We have heard concerns from a number of sources regarding the recent re-pricing of Norvir® (ritonavir). Over the past eight weeks, Abbott representatives have met with hundreds of members of the HIV community, including members of the HIV Medicine Association (HIVMA), American Academy of HIV Medicine (AAHIVM) and other HIV care providers; patients; advocates, including the AIDS Treatment Activist Coalition (ATAC); private and public payers, including the National Alliance of State and Territorial AIDS Directors (NASTAD); and government officials.

We have listened carefully to the concerns you have expressed and have taken your concerns to heart. We recognize that our communication regarding this re-pricing was not well handled. Please accept our apology.

Following is a summary of the issues that you have identified and the actions we have developed to address your specific concerns regarding:

- I. Patient Access
- II. Future of HIV Drug Development
- III. Drug Pricing

**I. Patient Access:** Abbott is committed to ensuring that every patient has unrestricted access to Norvir.

- As you know, we have committed to freeze the price of Norvir soft gelatin capsules at its former price for AIDS Drug Assistance Programs (ADAPs) through June 2005.
  - *Abbott now commits to freeze the price to ADAPs for Norvir soft gelatin capsules permanently.*
  - *Abbott also pledges to keep Norvir soft gelatin capsules on the market permanently, ensuring that public programs, such as ADAPs and Medicaid, continue to have this as a low-cost alternative.*
  - *Abbott will continue to provide Norvir free to any ADAP-eligible patient on a waiting list.*
- To date, formularies, co-payments, co-insurance, premiums, and access for HIV patients receiving Norvir remain unchanged. Antiretrovirals comprise just 1.5 percent of the nation's private payer pharmacy budget, and at its new price, Norvir accounts for just .02 percent of this budget<sup>1</sup>. While annual patient out-of-pocket expense is unchanged, patients with co-insurance (representing less than five percent of privately insured patients<sup>2</sup>) have experienced an increase in their initial out-of-pocket expenses at pharmacies.
  - *To address this, Abbott commits to making a 30-count bottle available to patients as soon as possible, in addition to the 120-count bottle available today. The 30-count bottle will also make dispensing more convenient.*
- For patients without prescription drug coverage:
  - *Abbott expanded its Patient Assistance Program (PAP) to ensure that any patient without drug coverage can get Norvir for free, regardless of their financial status.*

- *In addition, Abbott will provide Norvir® (ritonavir) free to anyone who has exceeded his or her coverage maximum for annual prescription drug benefits.*
- *These expanded benefits will be in place permanently.*

Applications for the Norvir PAP are available at Norvir.com, AbbottVirology.com, through any Abbott representative, or by dialing (800) 222-6885. Since the re-pricing on December 4, 2003, 100 percent of eligible PAP applications have been approved, usually within 24 hours, with drug shipping in 2-3 days.

**II. Future HIV Drug Development:** Abbott is committed to identifying and developing new antiretroviral compounds to increase and enhance patient treatment options.

- *To address the potential impact on the cost of future drug development, Abbott will provide Norvir 100 mg soft gelatin capsules for use in clinical development trials with new chemical entities, at the former price of \$1.71 – or less.*
- *Abbott also pledges to approach companies that have salvage compounds in development to explore options that will ensure that these therapies are affordable to patients upon market availability.*

We are proud of our 20-year history of pioneering contributions in HIV therapy and diagnostics, and feel that the important role of Norvir, coupled with our work in R&D, are part of the solution. Abbott's vision for HIV treatment is to develop a one-pill regimen dosed daily that is also tolerable and potent. We have a proven track record of success, having internally discovered and developed two protease inhibitors (PIs).

Today, we have more than 200 scientists dedicated to antiviral R&D. For these scientists, finding more and better HIV medicines is their life's work. Since this re-pricing, we have increased our antiviral R&D investment and have world-renowned scientists actively working on:

- *Discovering and developing new HIV protease inhibitors;*
- *Exploring new oral hepatitis C virus (HCV) compounds, focusing on polymerase; and*
- *Developing new formulations of both of our HIV products, with the goal of developing products that can be stored at room temperature, and improve dosing and tolerability for patients.*

### **III. Drug Pricing:**

Drug pricing is complex. The HIV community is facing increased financial pressures driven by escalating economics.

- Globally, there are greater demands for affordable access, and more patients to educate and treat;
- In addition, the need for indigent care in the U.S. is greater than ever; and
- The cost of bringing new drugs forward is more expensive, and complicated by increasing regulatory requirements.

Norvir plays a central role in the treatment of HIV. While the number of patients receiving Norvir as a boosting agent has grown over time, there has been a steady decline in sales due to the significant reduction in dose, with the majority of patients now taking 100 mg daily, as opposed to the initial 1200 mg daily. At the same time, the value of Norvir to patients with HIV has increased significantly. Abbott has taken this re-pricing step with Norvir in order to come to terms with these economic realities, while others have addressed this through the premium pricing of their new drugs.

Even at the new price, Norvir, at its most commonly used dose of 100 mg, is most often the lowest cost component of a PI-based regimen, and represents a fraction, typically one-third to one-fifth, of the daily cost of many typical HIV therapies.

To illustrate the value of Norvir to patients, in a recent article in *Antimicrobial Agents & Chemotherapy*<sup>3</sup>,  $C_{min}$  values of a recently approved protease inhibitor were increased 7.7-fold with the addition of 100 mg of Norvir. Applying linear kinetics, to achieve this same drug level without Norvir, a patient may need to take up to eight times more of this protease inhibitor. Assuming a patient was able to tolerate such a dose, it would be cost prohibitive, at more than \$150 a day.

Ultimately, the re-pricing of Norvir, coupled with the additional steps we've outlined, ensure that we can continue to work together to make advances in the treatment of HIV/AIDS and to serve the best interests of patients.

In summary, we are taking the following actions to further enhance patient access and the future of HIV research:

1. Permanently freezing Norvir soft gelatin capsule at the former price for ADAPs;
2. Making Norvir soft gelatin capsules available permanently;
3. Committing to provide a 30-count dispensing bottle to improve patient convenience and affordability;
4. Offering free Norvir via the only Patient Assistance Program without income requirements;
5. Giving free Norvir to patients who exceed their annual drug coverage maximum;
6. Freezing the cost of Norvir soft gelatin capsules at no greater than \$1.71 per 100 mg for use in clinical development with new chemical entities;
7. Reaching out to companies that have salvage compounds in development to explore options that will ensure that these therapies are affordable to patients upon market availability; and
8. Dedicating more than 200 world-renowned scientists to pursuing new compounds focused on HIV protease and HCV polymerase and to reformulating improved versions of our antiretroviral products.

Abbott is dedicated to continuing the fight against HIV in conjunction with you and the entire HIV community. Please do not hesitate to contact us by calling (847) 935-4100. Thank you for your continued partnership.

Sincerely,



John Leonard, M.D.  
Vice President  
Global Pharmaceutical Development



Jesus Leal  
Vice President and General Manager  
Abbott Virology

*Please see important safety and full prescribing information.*

[Kaletra® \(lopinavir/ritonavir\) Full Prescribing Information](#)  
[Norvir® \(ritonavir\) Full Prescribing Information](#)

<sup>1</sup> IMS, Retail & Providers Perspectives, Accessed November 2003

<sup>2</sup> Verispan HIV Therapy Audit, Q3 2003

<sup>3</sup> Saah AJ, et al; *Antimicrobial Agents & Chemotherapy*; October 2001; 45 (10); 2710-5\

## **Norvir® (ritonavir) Indication and Safety Information**

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 nonsedating 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
bepiridil	flecainide	propafenone	triazolam
cisapride			