



## IMPORTANT PRESCRIBING INFORMATION

## GlaxoSmithKline

PO Box 13398 Five Moore Drive Research Triangle Park North Carolina 27709-3398

www.gsk.com

## Re: Discontinuation of AGENERASE® (amprenavir) Oral Solution and 50 mg Capsules in the US

Dear Healthcare Provider:

This letter is intended to inform you that GlaxoSmithKline will be discontinuing the sale of AGENERASE® (amprenavir) Oral Solution and 50 mg Capsules in the US by the end of October 2007. This action is not the result of any safety or efficacy issues regarding these products.

GlaxoSmithKline has taken this action because the clinical demand for AGENERASE® (amprenavir) Oral Solution and 50 mg Capsules has diminished significantly, and because the US Food and Drug Administration (FDA) recently approved LEXIVA (fosamprenavir) Oral Suspension for treatment of HIV-1 infection, including dosing recommendations for children ages 2 to 18 and for adults with hepatic impairment. LEXIVA is the prodrug of AGENERASE. Both AGENERASE and LEXIVA are indicated in combination with other antiretroviral agents for the treatment of HIV infection.

Because of this discontinuation, please refrain from initiating treatment with AGENERASE Oral Solution or 50 mg Capsules in your patients with HIV infection. We encourage you (or the prescribing health care provider) to discuss appropriate alternative protease inhibitors or antiretroviral treatment regimens with your patients currently receiving AGENERASE Oral Solution or 50 mg Capsules.

LEXIVA may be an appropriate alternative option when transitioning your patients from the AGENERASE Oral Solution or 50 mg Capsules as LEXIVA is the prodrug of AGENERASE. LEXIVA Oral Suspension is available as a 50 mg/mL liquid preparation. If you wish to transition your patients to LEXIVA Oral Suspension, LEXIVA dosing may be initiated at the time of the next scheduled AGENERASE dose, without the need for a wash-out period or loading dose.

In pediatric patients at least 2 years of age already receiving AGENERASE Oral Solution (without ritonavir), the appropriate dose of LEXIVA Oral Suspension without ritonavir is 30 mg/kg twice daily, up to the adult maximum dose of LEXIVA 1400 mg twice daily. LEXIVA may also be administered with ritonavir to pediatric patients at least 6 years of

For additional information regarding LEXIVA Oral Suspension, including dosing information for adults with hepatic impairment who are receiving AGENERASE 50 mg Capsules or Oral Solution, please see the full prescribing information.

Amprenavir and fosamprenavir contain a sulfonamide, and patients with a known sulfonamide allergy should be treated with caution. Caution should be exercised when administering LEXIVA to patients with hepatic impairment. In patients receiving protease inhibitors (including amprenavir and LEXIVA), hyperglycemia, diabetes mellitus, immune reconstitution syndrome, acute hemolytic anemia and spontaneous bleeding in hemophiliacs have been reported. Severe and life-threatening drug interactions could occur, and skin reactions including Stevens-Johnson syndrome have occurred with amprenavir and fosamprenavir. Redistribution/accumulation of body fat has been observed in patients receiving antirctroviral therapy. The causal relationship, mechanism, and long-term consequences of these events are currently unknown. Please see the enclosed full prescribing information for LEXIVA Oral Suspension.

GlaxoSmithKline is committed to providing you with current product information for the management of your patients with HIV infection. You can assist us in monitoring the safety of our products by reporting adverse reactions to GlaxoSmithKline at 1-888-825-5249 or to FDA's MedWatch program by telephone at 1-800-332-1088, by fax at 1-800-332-0178, via www.FDA.gov/medwatch, or by mail to MedWatch, The FDA Safety Information and Adverse Event Reporting Program, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852-9787.

If you have questions about this information or want additional medical information regarding LEXIVA or AGENERASE, please contact the GSK Response Center at 1-888-825-5249. Thank you for your cooperation and understanding.

Sincerely,

John Pottage, M.D.

Vice President, Viral Diseases

US HIV Clinical Development, ID MDC