

CAREMARK TrendsRx® Alert

What's new...What's next...What to do now

August 2003

NEW DRUG APPROVAL

Levitra™ (vardenafil) & **PRE-DRUG APPROVAL** Cialis® (tadalafil)

Levitra® (vardenafil, Bayer and GlaxoSmithKline) was approved in August 2003 by the United States (US) Food and Drug Administration (FDA) for the treatment of erectile dysfunction (ED). Cialis® (tadalafil, Eli Lilly and ICOS Corp.) is expected to be approved also for ED, later in the year or early 2004. These two drugs are in the same drug class as Viagra® (sildenafil, Pfizer), phosphodiesterase V (PDE-5) inhibitor. PDE-5 is an enzyme that plays a role in ED. There appear to be a few differences between these two new drugs and Viagra. Levitra and Cialis are thought to more specifically target PDE-5. This may lead to better efficacy and fewer side effects than Viagra. Cialis remains in the body much longer than Viagra. Levitra remains in the body just slightly longer than Viagra. The recommended dose for Levitra is 10 mg taken orally 1 hour before sexual activity. The exact dosing for Cialis has not yet been established, but is thought that it will also be taken as needed before sexual activity. Common adverse events with Levitra and Cialis are similar to those occurring with Viagra, and include headache, flushing, and abdominal discomfort. Similar to Viagra, Levitra and Cialis should not be used in men receiving certain nitrate drugs. The average wholesale prices (AWP) for Levitra and Cialis will not be available until their launch.

BACKGROUND

Erectile dysfunction (ED) affects about 20 to 30 million men in the US. To date, Viagra has been the only oral drug available to treat ED. As seen in preliminary clinical studies, Levitra and Cialis appear to be safe and effective in the treatment of ED. However, it is not yet clear whether Levitra and Cialis will have a lower incidence of side effects than Viagra.

CAREMARK RESPONSE

- Levitra and Cialis will be available through both mail service and retail channels.
- For clients with plan restrictions for Viagra, including quantity limits, Caremark recommends similar class restrictions for Levitra and Cialis.
- For clients with CustomCare Mail, Caremark will include Levitra and Cialis in the same programs that target Viagra.

CONTACT

For more information call your Caremark account representative.

Please Note: This document provides a brief overview of the subject. Please refer to the manufacturer's full prescribing information for a complete discussion of the product. This review is provided as a reference only, and is based in part on information derived from third parties.