

CAREMARK TrendsRx[®] Alert

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

APRIL 2004

DRUG APPROVAL

Namenda[™] (memantine hydrochloride)

Namenda[™] (memantine hydrochloride, Forest Laboratories) was approved in October 2003 by the United States (U.S.) Food and Drug Administration (FDA) for the treatment of moderate to severe dementia of the Alzheimer's type. It is the first drug in a new class of medicines called NMDA receptor antagonists, and works differently than other medicines currently available to treat Alzheimer's disease. It works by blocking a specific brain chemical known as glutamate, which at abnormal levels, is thought to be responsible for causing brain cells to not function properly. Namenda is also the first medicine to be approved for moderate to severe stages of Alzheimer's disease, whereas the other medicines available have been approved for mild to moderate stages. Namenda is recommended to be dosed 5 mg daily and gradually increased to a target dose of 20 mg daily, which is given as 10 mg twice daily. A titration pack containing 28 of the 5 mg tablets and 21 of the 10 mg tablets is also available for individuals starting Namenda for the first time. The titration pack will typically last 28 days. Additional clinical studies are underway to determine different dosing schedules and indications for Namenda. The most common adverse events for Namenda were dizziness, confusion, headache and constipation. Namenda was made available in January 2004. The average wholesale price (AWP) for Namenda is \$279.00 for a 30-day supply for the 20 mg daily dose.

BACKGROUND

It is estimated that approximately 4.5 million Americans have Alzheimer's disease. Alzheimer's disease usually begins around 60 years of age and continues to get progressively worse. There are several stages of Alzheimer's disease that are defined by the different symptoms seen throughout the progression of the disease. The three main stages of Alzheimer's disease are mild/early, moderate and severe. Until now, the only treatments available in the U.S. were a group of medicines known as cholinesterase inhibitors. Cholinesterase inhibitors work by blocking the breakdown of a chemical in the brain, acetylcholine, which is needed for memory, thought and judgment. These medicines are used to treat mild to moderate stages of Alzheimer's Disease. Clinical trials have shown Aricept[®] (donepezil), a cholinesterase inhibitor, may be used in combination with Namenda. Namenda is the first medicine of its kind for the treatment of moderate to severe Alzheimer's disease.

CAREMARK RESPONSE

Based on currently available data, Caremark recommends considering coverage of Namenda under your prescription benefit.

Namenda will be available through both mail service and retail channels.

Caremark will monitor Namenda utilization and develop clinical programs as warranted.

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.