MEMANTINE HYDROCHLORIDE EXTENDED-RELEASE CAPSULES.

INDICATIONS AND USAGE

Memantine hydrochloride extended-release capsules are indicated for the treatment of moderate to severe dementia of the Alzheimer’s type.

Dosage and Administration

The recommended dose of memantine hydrochloride extended-release capsules 7 mg once daily, which should be swallowed whole. Memantine hydrochloride extended-release capsules are contraindicated in patients with known hyper敏itivity to memantine hydrochloride or to any component of the capsules.

If the recommended starting dose of memantine hydrochloride extended-release capsules is 7 mg once daily the dose should be increased to 14 mg once daily after 1 week. The minimum recommended interval between dose increases is one week (2.1).

CONTRAINdications

CONTRAINDICATIONS

Memantine hydrochloride extended-release capsules are contraindicated in patients with known hyper-sensitivity to memantine hydrochloride or to any component of the capsules.

— The recommended starting dose of memantine hydrochloride extended-release capsules was increased to 14 mg once daily. If the patient experiences an adverse reaction, the dose can be decreased to 7 mg once daily. The minimum recommended interval between dose increases is one week (2.1).

ADVERSE REACTIONS

The most commonly observed adverse reactions occurring at a frequency of at least 5% and greater than placebo were dizziness, constipation, and urinary incontinence (3).

DRUG INTERACTIONS

Drug interactions include:

1. Memantine is well absorbed after oral administration and has linear pharmacokinetics over the dose range of 28 mg to 120 mg once daily.

2. Memantine is a high-affinity antagonist at the N-methyl-D-aspartate (NMDA) receptor.

3. Memantine has not been systematically evaluated in patients with a seizure disorder. In clinical trials, the most frequently reported seizure was dizziness, at a rate of 1.5%.

4. The most commonly observed adverse reactions occurring at a frequency of at least 5% and greater than placebo were dizziness, constipation, and urinary incontinence (3).

5. Memantine has not been evaluated in patients with a seizure disorder. In clinical trials, the most frequently reported seizure was dizziness, at a rate of 1.5%.

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15. Memantine has not been evaluated in patients with a seizure disorder. In clinical trials, the most frequently reported seizure was dizziness, at a rate of 1.5%.

16. The most commonly observed adverse reactions occurring at a frequency of at least 5% and greater than placebo were dizziness, constipation, and urinary incontinence (3).

17. Memantine has not been evaluated in patients with a seizure disorder. In clinical trials, the most frequently reported seizure was dizziness, at a rate of 1.5%.
The effectiveness of memantine hydrochloride extended-release capsules as a treatment for moderate to severe Alzheimer’s disease was assessed in a 24-week, double-blind, placebo-controlled study. The study evaluated the ability of memantine hydrochloride extended-release capsules to improve cognitive performance and global clinical status in patients with Alzheimer’s disease. The study was a randomized, placebo-controlled, parallel-group trial comparing memantine hydrochloride extended-release capsules with placebo. The study population included patients with Alzheimer’s disease who had a baseline CIBIC-Plus (Clinical Interview-Based Impression of Change) score of 2, indicating moderate to severe dementia. The CIBIC-Plus is a caregiver-rated instrument that assesses overall clinical status, functional (including activities of daily living), cognitive, and behavioral. The trial included 360 patients who were randomly assigned to receive memantine hydrochloride extended-release capsules 28 mg/day or placebo while still receiving an AChEI (acetylcholinesterase inhibitor).

The effectiveness of memantine hydrochloride extended-release capsules was evaluated using the CIBIC-Plus and the Alzheimer’s Disease Cooperative Study-Activities of Daily Living (ADCS-ADL) scales. The CIBIC-Plus is a validated instrument that assesses changes in clinical status over time. The ADCS-ADL is a validated instrument that assesses changes in activities of daily living. The study showed that memantine hydrochloride extended-release capsules produced a significant improvement in cognitive performance and global clinical status compared to placebo.

Study Results

The CIBIC-Plus was used to assess the overall clinical status of patients, and the ADCS-ADL was used to assess changes in activities of daily living. The study also used the Alzheimer’s Disease Assessment Scale—Cognitive Subscale (ADAS-Cog) as a measure of cognitive function. The ADAS-Cog is a validated instrument that assesses cognitive function in patients with Alzheimer’s disease.

The study showed that memantine hydrochloride extended-release capsules produced a significant improvement in cognitive performance and global clinical status compared to placebo. The mean difference in change from baseline in CIBIC-Plus score at 24 weeks was 1.09 units in the memantine group compared to 0.41 units in the placebo group (p < 0.001). The mean difference in change from baseline in ADCS-ADL score at 24 weeks was 7.0 units in the memantine group compared to 3.3 units in the placebo group (p < 0.001).

Safety

The most common adverse events reported in the study were dizziness, fall, asthenia, nausea, and nasopharyngitis. The incidence of adverse events was similar in the memantine and placebo groups.

Conclusion

Memantine hydrochloride extended-release capsules produced a significant improvement in cognitive performance and global clinical status compared to placebo. The treatment was well tolerated, with a similar incidence of adverse events in the memantine and placebo groups. Memantine hydrochloride extended-release capsules may be an effective treatment for moderate to severe Alzheimer’s disease.