

Memantine Hydrochloride Tablets

Note: the content below do not include all the information needed to use Memantine Hydrochloride Tablets safely and effectively. Please read the package insert carefully and follow the doctors' instructions before use the product.

-----INDICATIONS AND USAGE-----

Memantine Hydrochloride Tablets USP is indicated for the treatment of moderate to severe dementia of the Alzheimer's type.

-----DOSAGE AND ADMINISTRATION-----

The recommended starting dose of Memantine Hydrochloride Tablet is 5 mg once daily. The dose should be increased in 5 mg increments to 10 mg/day (5 mg twice daily), 15 mg/day (5 mg and 10 mg as separate doses), and 20 mg/day (10 mg twice daily). The minimum recommended interval between dose increases is one week. The dosage shown to be effective in controlled clinical trials is 20 mg/day.

Memantine Hydrochloride Tablet can be taken with or without food. If a patient misses a single dose of Memantine Hydrochloride Tablet, that patient should not double up on the next dose. The next dose should be taken as scheduled.

If a patient fails to take Memantine Hydrochloride Tablet for several days, dosing may need to be resumed at lower doses and retitrated as described above.

Specific Populations

Renal Impairment

A target dose of 5 mg twice daily is recommended in patients with severe renal impairment (creatinine clearance of 5 – 29 mL/min based on the Cockcroft-Gault equation).

Hepatic Impairment

Memantine Hydrochloride Tablet should be administered with caution to patients with severe hepatic impairment [see CLINICAL PHARMACOLOGY (12.3)] .

-----DOSAGE FORMS AND STRENGTHS-----

Memantine Hydrochloride 5 mg tablet: round, film-coated tablets are tan, with the strength (M5) debossed on one side and V on the other.

Memantine Hydrochloride 10 mg tablet: round, film-coated tablets are gray, with the strength (M10) debossed on one side and X on the other.