The Carlat Psychiatry Report

RAZADYNE (galantamine) Fact Sheet

Manufacturer: Janssen; patent expires 2008.

Indications:

- Mild to moderate Alzheimer's dementia.
- Used off-label for both mild cognitive impairment and severe dementia.

Mechanism: Acetylcholinesterase inhibitor, stimulates nicotine receptors.

Dosing:

- Supplied as:
  - Immediate-release (IR): 4 mg white, 8 mg pink, 12 mg orange-brown tablets.
  - Extended-release (ER): 8 mg white, 16 mg pink, 24 mg orange-brown capsules.
  - Oral solution available in 4 mg/mL strength.
- IR: start at 4 mg BID, increase to 8 mg BID after four weeks. If needed, increase to 12 mg BID after another 4 weeks.
- ER: start at 8 mg QD, increase to 16 mg QD after four weeks. If needed, increase to 24 mg QD after another 4 weeks.
- You may need to decrease the dose in both hepatic and renal impairment.

Side Effects:

- Most common: nausea, appetite loss, diarrhea.
- FDA advisory noted a higher mortality rate in patients with mild cognitive impairment (MCI) taking Razadyne (1.5%) *versus* those randomly assigned to placebo (0.5%).
- May aggravate stomach ulcers (potential class effect of all cholinesterase inhibitors).
- Pregnancy risk category B.

Drug-drug interactions:

- Paxil and other 2D6 inhibitors may increase levels.
- 3A4 inducers such as Tegretol may decrease levels.

Pharmacokinetics:

- Metabolized hepatically by P450 2D6 and 3A4.
- Half-life 7 hours.

Laboratory monitoring:

- None required

Pearls: Most clinicians use the ER version exclusively because it can be dosed once a day.