



## Patient Information Sheet

# Galantamine hydrobromide (marketed as Razadyne, formerly Reminyl)

This is a summary of the most important information about Razadyne. For details, talk to your healthcare professional.

- Are having surgery, including dental surgery that will require anesthesia.

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**FDA ALERT [3/2005]: FDA and other international health authorities are reviewing the safety of Razadyne after data from two clinical studies indicated that people taking the drug had a higher death rate than those taking a placebo (sugar pill). Based on this information, FDA has asked the manufacturer to revise the labeling. Please ask your healthcare provider if Razadyne is right for you.**

*This information reflects FDA's preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about, this information. FDA intends to update this sheet when additional information or analyses become available.*

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### What Is Razadyne?

Razadyne is a medicine used to treat mild to moderate Alzheimer's disease.

### Who Should Not Take Razadyne?

You should **NOT** take Razadyne if you:

- Have severe liver or kidney disease

### What Are The Risks?

The most frequent side effects experienced in patients taking Razadyne were:

- Nausea
- Vomiting
- Diarrhea
- Loss of appetite
- Weight loss

### What Should I Tell My Healthcare Professional Before Taking Razadyne?

Tell your healthcare professional if you:

- Have or have ever had asthma; an enlarged prostate; stomach ulcers; or heart, kidney, liver, or lung disease
- Have seizures or a history of seizures
- Are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking Razadyne, call your healthcare professional.

### Are There Any Interactions With Drugs or Foods?

Tell your healthcare professional about all the medicines you take, including prescription and over-the-counter drugs, and supplements. Your healthcare professional may have to adjust your dose or watch you more closely if you take any of the following medications:

- Amitriptyline
- Fluoxetine
- Fluvoxamine
- Quinidine
- Cimetidine
- Ketoconazole
- Erythromycin
- Paroxetine

### How Do I Take Razadyne?

Razadyne comes as a tablet and an oral solution to take by mouth. It is usually taken twice a day, preferably with the morning and evening meals. Your healthcare professional will start you on a low dose of Razadyne and gradually increase your dose over time, with a minimum of 4 weeks between each increase in dose. This helps to minimize the amount of side effects.

### Is There Anything Else I Need To Know?

Razadyne may make you drowsy. Do not drive a car or operate machinery until you know how Razadyne affects you.

