

Questions about ARICEPT? We have Answers!

Prepared by Mylène Horth, BPharm, MSc, medical information officer, Pfizer Canada Inc., and reviewed by Serge Gauthier, MD, FRCPC

The primary goal of this article is to answer some of the technical and practical questions you may have concerning ARICEPT. The following questions represent some of the most frequently asked questions by health care professionals, patients and caregivers, received by the Safety and Medical Information department at Pfizer Canada Inc.

Q Is it possible to take Aricept in the morning instead of at bedtime?

Taking Aricept at bedtime may minimize gastro-intestinal (GI) side effects or nausea observed with some patients in the first weeks of treatment. There could be situations, however, when a bedtime dosage is not possible because of a morning visit by a caregiver or nurse, or sleep disturbance. In these cases, a morning dosage is perfectly acceptable and will not change the efficacy of Aricept.

Q Do GI side effects secondary to Aricept (e.g., nausea, diarrhea) persist for a long time?

GI side effects may appear in the first weeks of treatment with Aricept. A few solutions are suggested to minimize these adverse events, such as bedtime dosing and taking Aricept with food. In clinical trials, adverse effects were often mild and generally disappeared within a few weeks with continued treatment. The majority of the patients usually developed tolerance to GI side effects. Temporary symptomatic treatment may be necessary in some cases where these adverse events are persistent despite the use of the above-mentioned preventative measures.

Q How long does it take before the effects of Aricept are visible?

Based on the available clinical information, cognitive effects may be observed within the first month of treatment with Aricept. Clinical benefits in terms of functional improvement may take longer to appear. Beneficial symptomatic effects versus placebo are consistently more apparent after 12 weeks of treatment.

Q Why should patients be maintained on Aricept 5 mg daily for four to six weeks before increasing the dose to 10 mg daily?

According to an open-label study, the rate of common adverse events was lower in patients who received a 5 mg daily dose for six weeks prior to initiating treatment with 10 mg daily than those seen in patients who received 10 mg daily after only one week of treatment with 5 mg daily. In this study, the rate of adverse events with 10 mg daily was comparable to the rate noted in patients treated with 5 mg daily. Patients are, therefore, recommended to maintain the initial dose of 5 mg daily for four to six weeks. After this period, if the patient is tolerating the 5 mg dosage and it is concluded that a higher dosage will be beneficial to the patient, then dosage may be increased to 10 mg daily.

Q How should Aricept be discontinued, if necessary?

Aricept has a long half-life and is eliminated very slowly. Consequently, gradual tapering of Aricept is not necessary for a patient who has to discontinue the medication. The half life of Aricept is 72 hours and it may take two weeks or more for the drug to be completely eliminated from the system.

Q Is there any information concerning the use of high doses of Aricept (> 10 mg)?

The maximum recommended dosage for Aricept is 10 mg daily. According to a multinational Phase III clinical trial, Aricept 5 and 10 mg daily demonstrated significant improvements in both cognitive and global functioning. Aricept 10 mg, however, has shown an even greater improvement.

A comprehensive literature search did not identify any published information on the use of higher dosage of Aricept. In fact, the efficacy and safety of high doses of Aricept (> 10 mg daily) have not been established in humans.

Q Can Aricept be used in patients with severe AD?

Aricept is not indicated in patients with severe AD because its efficacy and safety have not been established in this population at this time. In clinical trials conducted with Aricept, patients were included if the disease severity was rated as mild to moderate. Severity was established by a mini-mental state examination (MMSE) score between 10 and 26 and a Clinical Dementia Rating (CDR) of one or two. There is currently a clinical trial in Canada to assess the efficacy and safety of Aricept in moderate to severe AD.

Q Is Aricept indicated for the treatment of vascular dementia?

Aricept is officially indicated for the treatment of mild to moderate AD only. Unfortunately, there is no published study on the use of Aricept in vascular dementia at the present time. There is currently a clinical trial underway, conducted by Eisai in the United States, to assess the efficacy of Aricept in this type of dementia. Preliminary results are not yet available.

Q Is there any study on the use of Aricept in patients suffering from Down's Syndrome?

At the present time, Pfizer Canada Inc. and Eisai have not conducted clinical studies in order to assess the role of Aricept in the prevention or treatment of AD in patients with Down's syndrome. For now, trials have involved adult patients suffering from mild to moderate AD only. No information, therefore, is available on the efficacy or safety of Aricept in patients suffering from Down's syndrome.

NOTICEBOARD

The Alzheimer Society of Canada's 21st Annual Conference

Address your most pressing issues to federal decision makers on April 22, 1999 in Ottawa, Ontario. The Alzheimer Society of Canada will be holding their 21st Annual Conference at the Citadel Hotel. The objectives are to facilitate a dialogue between researchers and caregivers (both formal and informal) and to broaden knowledge regarding:

- biomedical and psychosocial research
- public policy issues
- support and educational problems
- organizational development

For more information, please contact the Alzheimer Society at 1-800-616-8816.

Book Review—Pharmacotherapy of Alzheimer's Disease

A new Canadian book release, *Pharmacotherapy of Alzheimer's Disease*, will update you on developments in pharmacotherapy treatment of Alzheimer's Disease (AD). The book's editor is Dr. Serge Gauthier, from the McGill Centre for Studies in Aging, Montreal, Quebec. Chapters dedicated to drug development, research and practice, trial designs, regulatory issues in anti-dementia drug development, social and ethical considerations are the some of the topics explored in this new book.

Translating Advances Into Hope: The 12th Annual Alzheimer Symposium

The Alzheimer Society of Toronto and the Rehabilitation Institute of Toronto will be holding their 12th Annual Alzheimer Symposium: *Translating Advances Into Hope* on Friday, January 22, 1999 from 8:30 am to 4:15 pm. The one-day event is open to hospital clinicians, community agency staff, managers and family members of patients with Alzheimer's Disease. Topics of discussion will include:

- The Development of Medication to Stabilize Dementia
- Report on Canadian Consensus Guidelines for Dementia Care
- New Approaches to Morning Care
- The Effect of Alzheimer's Disease on Families and Caregivers
- Using Illogical Logic, Humor and Positive Body Language in Redirecting People with Alzheimer's Disease
- Living Space Designs for Dementia Specific Environments

Brochures can be obtained by calling: (416) 597-4494 ext. 3693.