

Donepezil rapidly dissolving tablet

Product:

DONEPEZIL (Aricept RDT®) 5 mg,
10 mg rapidly dissolving tablet

Class of drugs:

Cholinesterase inhibitor

Indication:

Treatment of Alzheimer's disease

Manufacturer:

Pfizer Canada Inc.

CED Recommendation

The CED recommended that donepezil rapidly dissolving tablet (Aricept RDT) not be listed on the Ontario Drug Benefit (ODB) Formulary, on the basis that donepezil regular tablet is already available on the Formulary. This new dosage form provides little added therapeutic benefit, and its listing could potentially lead to inappropriate use.

Executive Officer Decision

Based on the CED's recommendation, the Executive Officer decided not to list donepezil rapidly dissolving tablet (Aricept RDT) on the ODB Formulary.

Status

No funding through the Ontario Public Drug Programs.

Highlights of Recommendation:

- ◆ Donepezil rapidly dissolving tablet (Aricept RDT) is a line-extension product. Regular donepezil (Aricept) tablet is available as a Limited Use benefit on the Ontario Drug Benefit Formulary for patients with mild to moderate Alzheimer's disease. The rapidly dissolving tablet melts on the tongue and may be used for Alzheimer's patients who have difficulty swallowing.
- ◆ The Committee noted that donepezil is only approved in Canada for patients with mild to moderate Alzheimer's disease. Given that patients with severe disease are the ones who have the most difficulty swallowing, the Committee was concerned that the rapidly dissolving tablet could be used inappropriately in patients with severe disease.
- ◆ The price of donepezil rapidly dissolving tablet (Aricept RDT) is the same as that for donepezil (Aricept) regular tablet (approximately \$4.80 per tablet). The Committee anticipated that a generic donepezil will soon be available at a lower price.
- ◆ **Overall, the Committee noted that donepezil rapidly dissolving tablet (Aricept RDT) offers little added therapeutic benefit and was concerned that funding may lead to inappropriate use in patients with severe Alzheimer's disease.**

Background:

Alzheimer's disease is a progressive, degenerative brain disease. It affects reason, judgment and memory.

Donepezil (Aricept) is thought to work by inhibiting cholinesterase, an enzyme that breaks down acetylcholine. Acetylcholine is a neurotransmitter that is important to memory function. People with Alzheimer's disease have lower levels of acetylcholine in their brains than people who do not have the disease.

At present, donepezil (Aricept) and donepezil rapidly dissolving tablet (Aricept RDT) are approved only for patients with early to moderate Alzheimer's disease.

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Detailed Discussion:

- ◆ The Health Canada approval for donepezil rapidly dissolving tablet (Aricept RDT) was based upon demonstration of bioequivalence to donepezil (Aricept) regular tablet. No new clinical studies were conducted for this line-extension product.
- ◆ The most common side effects for donepezil include nausea, diarrhea, insomnia, vomiting, muscle cramps, fatigue and loss of appetite and, occasionally, fainting.
- ◆ The Committee noted that donepezil is approved in the United States for the treatment of mild to moderate as well as severe Alzheimer's disease. In Canada, donepezil is currently approved for only mild to moderate disease. Given that patients with severe Alzheimer's disease are the ones who have the most difficulty swallowing, the Committee was concerned about off-label use in patients with severe disease. The Committee was unaware of any high quality data supporting the use of donepezil in the more advanced stages of Alzheimer's disease.
- ◆ Overall, the Committee noted that donepezil rapidly dissolving tablet (Aricept RDT) offers little added therapeutic value and was concerned that funding may lead to inappropriate use in patients with severe Alzheimer's disease.

CEDAC Recommendation:

(<http://www.cadth.ca/index.php/en/cdr/recommendations>)

The Canadian Expert Drug Advisory Committee (CEDAC) did not review donepezil rapidly dissolving tablet (Aricept RDT).



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