

Supplemental Approvals

Generic Name (Trade Name—Company)

December 31, 2010

Uses/Notes

Treatment of type 2 diabetes as an adjunct to diet and exercise as monotherapy or in combination with other oral antidiabetic agents

Bromocriptine

(Cycloset—Santarus)

Diabetes is new indication for old drug

The exact mechanism by which [bromocriptine](#) improves glycemic control is unknown; it may normalize aberrant hypothalamic neurotransmitter activities that induce, potentiate, and maintain the insulin-resistant, glucose-intolerant state. Data from four double-blind, placebo-controlled trials (one monotherapy and three add-on trials) involving more than 3,700 patients with type 2 diabetes showed that bromocriptine produced clinically significant improvements in glycosylated hemoglobin (A1C) (difference from placebo [range –0.4% to –0.6%]) and postprandial glucose, and more patients given bromocriptine reached an A1C goal of 7% or less compared with placebo. The recommended dose is 1.6–4.8 mg once daily. The tablets are currently available in pharmacies in a 0.8-mg strength.

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<http://www.aphanet.org/diabetes-new-indication-old-drug>

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