

CEDAC FINAL RECOMMENDATION and REASONS for RECOMMENDATION

AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM (Caduet™ – Pfizer Canada Inc.)

Description:

Caduet™ is a fixed dose combination of amlodipine and atorvastatin and is approved for use in patients for whom treatment with both amlodipine and atorvastatin is appropriate, specifically, patients at cardiovascular risk.

Dosage Forms:

Tablets containing amlodipine/atorvastatin in the following combinations: 5/10 mg, 5/20 mg, 5/40 mg, 5/80 mg, 10/10 mg, 10/20 mg, 10/40 mg and 10/80 mg.

Recommendation:

The Canadian Expert Drug Advisory Committee (CEDAC) recommends that Caduet™ be listed for patients who have been titrated to a stable combination of the separate components, amlodipine and atorvastatin.

Reasons for the Recommendation:

1. There were no randomized controlled trials (RCTs) that evaluated Caduet™. The Committee considered the results of two RCTs of 8 weeks duration which evaluated the efficacy and safety of amlodipine and atorvastatin, given individually and as a combination of the separate agents, in patients with hypertension and hyperlipidemia. Patients from these studies were subsequently entered into open-label extension phases with Caduet™ treatment for up to 64 weeks. During the RCT phase of the trials, concurrent treatment with amlodipine and atorvastatin was found to be safe and effective. The safety profile of Caduet™ during the open-label extension was similar to that observed with the individual agents during the RCT phase.
2. Caduet™ is bioequivalent to co-administration of the individual agents, amlodipine and atorvastatin.
3. The cost of Caduet™ is currently less than the cost of the individual components (cost savings of \$0.08 to \$1.05 per day depending on the dose).

Of Note:

1. The cost savings associated with Caduet™ use may be subject to change if generic amlodipine and/or atorvastatin products are approved for use and the Committee recommends that the listing status of Caduet™ be reviewed by individual drug plans at that time.
2. Both published and unpublished data were reviewed and taken into consideration in making this recommendation.