Canadian Agency for Drugs and Technologies in Health

Agence canadienne des médicaments et des technologies de la santé

CEDAC FINAL RECOMMENDATION on RECONSIDERATION and REASONS for RECOMMENDATION

EXTENDED-RELEASE NIACIN AND LOVASTATIN (Advicor® - Oryx Pharmaceuticals Inc.)

Description:

Advicor® is a fixed dose combination of extended-release niacin and lovastatin that is approved for use in the treatment of primary hypercholesterolemia and mixed dyslipidaemia in:

- Patients treated with lovastatin who require further triglyceride (TG) lowering or high-density lipoprotein (HDL)-raising who may benefit from niacin added to their regimen;
- Patients treated with extended-release niacin who require further LDL-lowering who may benefit from having lovastatin added to their regimen.

Dosage Forms:

Tablets containing 500 mg/20 mg or 1000 mg/ 20 mg of extended-release niacin/lovastain

Recommendation:

The Canadian Expert Drug Advisory Committee (CEDAC) recommends that Advicor® be listed.

Reasons for the Recommendation:

1. The Committee considered the results of two randomized controlled trials (RCTs) of 16 and 28 weeks duration utilizing different doses of Advicor®. Only the 28 week RCT used the Health Canada approved dose of Advicor®, a maximum of extended-release niacin 1000 mg and lovastatin 20 mg, in a total of 57 patients. In this study, the use of Advicor® resulted in statistically significantly greater reduction in triglycerides (TG), an elevation of high-density lipoprotein (HDL) cholesterol, and a similar reduction in low density lipoprotein (LDL) cholesterol compared to lovastatin alone. It also resulted in a significantly greater reduction in LDL and TG, and an elevation of HDL cholesterol compared to niacin alone.

2. Side effects with Advicor® are similar to those seen with the individual components of niacin and lovastatin. The use of extended-release niacin is associated with a reduced number of episodes of flushing compared to immediate-release niacin during the initial 12 weeks of therapy, although it is unclear if this difference persists over the long-term.

3. Hepatic toxicity, myopathy and rhabdomyolysis are the primary safety concerns with the combined use of lovastatin and extended-release niacin.

4. Advicor®, at the Health Canada approved dose of 20 mg lovastatin and 1000 mg niacin, is less expensive than the combined use of lovastatin and extended-release niacin (Niaspan®) and is similar in price to lovastatin and immediate-release niacin.

Of Note:

1. At the maximum approved dose of Advicor®, the degree of LDL cholesterol lowering may be suboptimal for some patients. It is unknown whether the improved lipid profile seen with Advicor® compared to lovastatin alone will affect cardiovascular or other morbidity or mortality as there are no trial data with these outcomes.

2. Both published and unpublished data were reviewed and taken into consideration in making this recommendation.