Canadian Expert Drug Advisory Committee
Final Recommendation and Reasons for Recommendation
Plain Language Version

Acamprosate calcium (Campral® – Prempharm Inc.)
Indication – Maintenance of Alcohol Abstinence

The information contained within this plain language version of the Canadian Expert Drug Advisory Committee (CEDAC) Final Recommendation and Reasons for Recommendation about this drug is based on the information found within the corresponding technical version of the CEDAC Final Recommendation and Reasons for Recommendation. Health care professionals and those requiring more detailed information are advised to refer to the technical version available in the CDR Drug Database on the CADTH web site (www.cadth.ca).

Drug

Acamprosate, commonly known as Campral, is approved by Health Canada for people who are dependent on alcohol but have stopped drinking, to help them continue to keep from drinking alcohol. Campral should be used as part of a treatment program that also includes counselling. It's not entirely clear how Campral works but it is believed to restore the natural balance of chemicals in the brain.

Dose

Campral is available in tablets. The recommended dose for adults is 666 mg of the drug (two tablets) three times each day. It is recommended that Campral be taken for up to one year.

CEDAC Recommendation

CEDAC recommended that Campral be listed for coverage by Canada's publicly funded drug plans only for patients who have not been drinking any alcohol for at least four days and who are unable to take ReVia™ (naltrexone) – another drug used to help people dependant on alcohol. Campral should be covered for no longer than one year of treatment.

Reasons for the Recommendation

- Some studies have shown that Campral helps patients to not drink better than no active medication (called a placebo).
- Other than patients who cannot take ReVia, the evidence does not suggest that Campral offers any advantage over ReVia in helping people abstain from drinking alcohol. One large study, evaluating higher doses of Campral and ReVia than approved in Canada, showed that the drug was not beneficial to patients attempting not to drink, whether or not Campral was combined with other therapies, such as counselling, to change their behaviour. The same study did show a benefit with ReVia treatment.

- Campral costs $4.80 each day which is almost the same as ReVia at $5.00 each day. Because it's unclear whether or not Campral works as well as ReVia, the Committee felt that Campral should only be listed for coverage in people who cannot take ReVia.

Summary of CEDAC Considerations

- When considering Campral, CEDAC considered a large review that combined the results of 17 smaller studies comparing Campral to placebo.
- When the results of all the studies were combined, Campral did improve how long patients went without drinking. But when each of the studies was looked at on its own, the results were less clear. Three studies showed a big improvement with Campral but about half of the studies showed no difference between patients treated with Campral and those treated with placebo.
- Many of the studies took place in treatment centres or hospitals, but three studies that took place in the community (where patients were not admitted to a hospital or treatment centre) showed no difference between patients taking Campral and those taking placebo.
- Up to half of the patients did not finish the trial in which they were taking part. This makes it difficult to know how well Campral works in helping patients not to drink.
- Four more studies on Campral, not included in the combined review of 17 studies, were also considered.
- Two of the studies lasting 12 weeks compared Campral, ReVia and placebo. One of these studies showed that Campral and ReVia improved how long patients went until their first drink and how long until they drank heavily compared with placebo. The other study showed no differences between Campral, ReVia or placebo.
- A study of Campral and ReVia at doses higher than approved in Canada was also reviewed by CEDAC. The study included 1383 patients in the United States who were not drinking that were not admitted to a treatment centre or hospital. The patients were treated with either Campral or ReVia (or both) or placebo for 16 weeks. Therapy such as counselling to help change their behaviour was also included for some patients. The patients were watched for up to a year to see whether their treatment made a difference in their drinking. The results showed that Campral did not have any effect on patients' drinking whether or not it was combined with other therapies (such as ReVia or counselling or both).
- None of the studies reviewed reported on the consequences of drinking alcohol such as death related to drinking, how patients functioned in their daily lives (with family or at work), or their quality of life.
- In general, patients did not report many side effects when taking Campral. However side effects related to suicide such as thoughts of suicide or attempting suicide were more common with Campral than with placebo. The chance of dying due to suicide was not different between the groups.

Background

CEDAC is a committee of the Canadian Agency for Drugs and Technologies in Health (CADTH). The committee is made up of drug evaluation experts and public members. CEDAC provides recommendations about whether or not drugs should be listed for coverage through the participating publicly funded drug plans; however, the individual drug plans make their own decisions about whether or not to cover a drug.

In making its recommendations, CEDAC decides if the drug under review ought to be covered by the participating public drug plans based on an evidence-informed review of the medication's effectiveness and safety, and based on an assessment of its cost-effectiveness in comparison with other available treatments.

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The manufacturer has reviewed this document and has not requested the deletion of any confidential information.