



Canadian Agency for
Drugs and Technologies
in Health

COMMON DRUG REVIEW

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

Sitagliptin (Januvia™ — Merck Frosst Canada Ltd.) Indication — Type 2 Diabetes

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](http://www.cadth.ca) on the CADTH website (www.cadth.ca).

Description of Drug

Sitagliptin (Januvia) is the first in a new class of drugs called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors) used to lower blood sugar. It works by stimulating the pancreas to release insulin and by decreasing the amount of sugar being produced by the liver, both of which lead to lower blood sugar. Januvia, used in combination with metformin, is approved for improving blood sugar levels in adult patients with type 2 diabetes in addition to diet and exercise when metformin plus diet and exercise do not adequately lower blood sugar.

Dose

Januvia is available in 100 mg tablets. The recommended dose is one tablet each day.

CEDAC Recommendation

CEDAC recommended that Januvia not be listed for coverage by the Canadian publicly funded drug plans, participating in the Common Drug Review.

CEDAC Reasons for the Recommendation

- Studies have shown that in the short term, Januvia combined with metformin reduces blood sugar and HbA1c (a measure of how well blood sugar has been controlled during the previous three months). However, there have been no studies looking at important, longer-term health outcomes for patients with type 2 diabetes who are treated with Januvia. So it's not known whether Januvia can prevent the complications of diabetes that may develop over time, including blindness, heart disease, and kidney problems.

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CEDAC Meeting — May 21, 2008
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- Januvia is not recommended for patients with moderate or severe kidney disease. Because there are no studies looking at the effects of long periods of treatment with Januvia, its long-term safety is not known. This is especially important given recent safety concerns about other drugs used to treat type 2 diabetes.
- The manufacturer of Januvia submitted a confidential price for the drug which is more expensive than many other drugs used to treat type 2 diabetes. The manufacturer suggested that Januvia could be listed for coverage by the publicly funded drug plans for patients who cannot take certain types of other drugs for type 2 diabetes together with metformin. However, there is little information on how well Januvia would work in these patients and whether it would be any better than other less expensive drugs for type 2 diabetes.

Summary of Committee Considerations

- CEDAC considered four studies comparing metformin plus Januvia with metformin plus no active medication (called a placebo) in adult patients with type 2 diabetes whose blood sugars were not well controlled. The studies lasted between 18 and 30 weeks.
- All four studies showed improvements in HbA1c with metformin plus Januvia compared with metformin plus placebo. More patients treated with metformin plus Januvia achieved the target (less than 7%) for the HbA1c test than those treated with metformin plus placebo.
- No trials have assessed important health outcomes in patients with type 2 diabetes such as heart disease, problems with the large or small blood vessels in the body, or death.
- When the four studies were extended for up to 54 to 104 weeks, the results suggested that blood sugars may not be as well controlled with Januvia with longer-term use.
- The trials did not reveal any important differences in side effects between Januvia and placebo, including episodes of severe low blood sugar levels, weight gain or loss, and serious complications due to treatment.
- One small trial looking at the effects of Januvia compared with placebo in patients with kidney disease suggested that these patients who received Januvia may have had higher rates of heart attack, abnormal heart rhythm, and death.
- Januvia is not recommended for use in patients with moderate or severe kidney disease.
- Januvia is more expensive than some other drugs that can be used with metformin, and it is uncertain if Januvia offers value when compared with these other drugs.

Background on CEDAC

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 decision 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 statements, conclusions, and views expressed herein do not necessarily represent the view of Health Canada, the federal government, any provincial or territorial government, or any pharmaceutical manufacturer.

The manufacturer has reviewed this document and has requested the deletion of confidential information.

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