



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Questions and answers on the use of Vokanamet in diabetic kidney disease

The European Medicines Agency has finalised its assessment of an application to approve a change to the indication of Vokanamet (canagliflozin/metformin) to include the treatment of kidney disease in patients with type 2 diabetes.

Although EMA's medicines committee (CHMP) did not recommend inclusion of this use, it agreed that relevant safety data from the study submitted with the application be included in the medicine's product information.

### **What is Vokanamet and what is it used for?**

Vokanamet is a medicine used, together with diet and exercise, to treat adults with type 2 diabetes whose disease is not satisfactorily controlled with metformin alone, or it is used in combination with other diabetes medicines when these medicines together with metformin are not providing adequate control of the diabetes. Vokanamet can also be used to replace canagliflozin and metformin given separately.

It contains the active substances canagliflozin and metformin and is available as tablets.

Vokanamet has been authorised in the EU since April 2014.

Further information on Vokanamet's current uses can be found on the Agency's website:  
[ema.europa.eu/en/medicines/human/EPAR/vokanamet](http://ema.europa.eu/en/medicines/human/EPAR/vokanamet)

### **What change had the company applied for?**

The company applied to extend the use of Vokanamet to include the treatment of chronic (long-term) kidney disease and albuminuria (protein in the urine) in adults with type 2 diabetes.

### **How does Vokanamet work?**

Type 2 diabetes is a disease in which the pancreas does not make enough insulin to control the level of glucose in the blood or when the body is unable to use insulin effectively. This leads to high levels of glucose in the blood.

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Vokanamet contains two different active substances, which work in different ways:

- canagliflozin works by blocking a protein in the kidneys called sodium glucose co-transporter 2 (SGLT2). SGLT2 absorbs glucose back into the bloodstream as the blood is filtered in the kidneys. By blocking the action of SGLT2, canagliflozin causes more glucose to be removed via the urine, thereby reducing the levels of glucose in the blood. Canagliflozin has also been shown to slow the progression of diabetic kidney disease. Canagliflozin as separate tablets has been authorised in the EU under the brand name Invokana since November 2013.
- Metformin works mainly by inhibiting glucose production and reducing its absorption in the gut. It has been available in the EU since the 1950s.

As a result of the action of both active substances, the blood glucose is reduced and this helps to control type 2 diabetes.

### **What did the company present to support its application?**

The company presented results from a main study, the CREDENCE study, in 4,401 patients with type 2 diabetes and diabetic kidney disease. The study compared the effects of using canagliflozin (at a dose of 100 mg per day) with those of placebo (dummy treatment), in addition to standard treatment of diabetic kidney disease, on the kidney and heart.

### **What were EMA's conclusions?**

EMA's medicines committee (CHMP) noted that the results of the CREDENCE study cannot be automatically applied to Vokanamet as the study only looked at canagliflozin and did not focus on the combination of canagliflozin and metformin. In addition, the CHMP noted that giving the dose of canagliflozin used in the study as the fixed dose combination Vokanamet would mean exceeding the maximum recommended dose of metformin if patients had moderately or severely reduced kidney function.

Relevant safety data from the main study will, however, be included in the product information for Vokanamet so that healthcare professionals have access to most up to date data on the effects of Vokanamet in patients with diabetes.

### **Does this outcome affect patients in clinical trials?**

The company informed the Agency that there are no consequences for patients in clinical trials using Vokanamet.