



19 September 2013
EMA/CHMP/564958/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Invokana canagliflozin

On 19 September 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Invokana (100 mg and 300 mg film-coated tablet) intended for the treatment of type 2 diabetes. This recommendation will now be forwarded to the European Commission, which will issue a legally binding decision. The applicant for this medicinal product is Janssen-Cilag International N.V.

The indication recommended by the CHMP is as follows:

“Invokana is indicated in adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as:

Monotherapy

When diet and exercise alone do not provide adequate glycaemic control in patients for whom the use of metformin is considered inappropriate due to intolerance or contraindications.

Add-on therapy

Add-on therapy with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control (see sections 4.4, 4.5, and 5.1 for available data on different add-on therapies).”

The active substance of Invokana, canagliflozin, is a blood glucose-lowering medicine. It works by blocking a protein in the kidney called the human sodium-glucose co-transporter-2 (SGLT2). This reduces glucose re-absorption in the kidney leading to glucose excretion in the urine, thereby lowering levels of glucose in the blood of patients with type 2 diabetes.

The most common side effects with Invokana are hypoglycaemia (when used in combination with insulin or a sulphonylurea), vulvovaginal candidiasis, urinary tract infection, and polyuria or pollakiuria (i.e., urinary frequency).

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.



A pharmacovigilance plan for Invokana will be implemented as part of the marketing authorisation.

The medicine is to be available only on prescription.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.