19 June 2025
EMA/CHMP/201774/2025
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (post authorisation)**

# Cabometyx

cabozantinib

On 19 June 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Cabometyx. The marketing authorisation holder for this medicinal product is Ipsen Pharma.

The CHMP adopted a new indication as follows:

Neuroendocrine Tumours (NET)

CABOMETYX is indicated for the treatment of adult patients with unresectable or metastatic, well differentiated extra-pancreatic (epNET) and pancreatic (pNET) neuroendocrine tumours who have progressed following at least one prior systemic therapy other than somatostatin analogues.

For information, the full indications for Cabometyx will be as follows:[2]

Renal cell carcinoma (RCC)

CABOMETYX is indicated as monotherapy for advanced renal cell carcinoma

- as first-line treatment of adult patients with intermediate or poor risk (see section 5.1),
- in adults following prior vascular endothelial growth factor (VEGF)-targeted therapy (see section 5.1).

Cabometyx, in combination with nivolumab, is indicated for the first-line treatment of advanced renal cell carcinoma in adults (see section 5.1).

Hepatocellular carcinoma (HCC)

CABOMETYX is indicated as monotherapy for the treatment of hepatocellular carcinoma (HCC) in adults who have previously been treated with sorafenib.

[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
[2] New text in bold

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Differentiated thyroid carcinoma (DTC)

CABOMETYX is indicated as monotherapy for the treatment of adult patients with locally advanced or metastatic differentiated thyroid carcinoma (DTC), refractory or not eligible to radioactive iodine (RAI) who have progressed during or after prior systemic therapy.

**Neuroendocrine Tumours (NET)**

**CABOMETYX is indicated for the treatment of adult patients with unresectable or metastatic, well differentiated extra-pancreatic (epNET) and pancreatic (pNET) neuroendocrine tumours who have progressed following at least one prior systemic therapy other than somatostatin analogues**.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.