EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 September 2018
EMA/CHMP/616909/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Cabometyx

cabozantinib

On 20 September 2018, 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:

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

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

> "Renal Cell Carcinoma (RCC)
>
> CABOMETYX is indicated for the treatment of advanced renal cell carcinoma (RCC):
>
> - in treatment-naïve adults with intermediate or poor risk (see section 5.1)
>
> - in adults following prior vascular endothelial growth factor (VEGF)-targeted therapy
>
> **Hepatocellular Carcinoma (HCC)**
>
> **CABOMETYX is indicated as monotherapy for the treatment of hepatocellular carcinoma (HCC) in adults who have previously been treated with sorafenib.**"

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

[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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