19 September 2024
EMA/CHMP/423595/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Pravafenix

fenofibrate / pravastatin sodium

On 19 September 2024, 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 Pravafenix. The marketing authorisation holder for this medicinal product is Laboratoires SMB s.a.

The CHMP adopted an extension to the existing indication to include maintenance treatment with moderate-intensity statins other than pravastatin. For information, the full indication will be as follows[2]:

> Pravafenix is indicated as an adjunct to diet and other non-pharmacological treatment (e.g. exercise, weight reduction) for the treatment of mixed hyperlipidaemia in adult patients at high cardiovascular risk to reduce triglycerides and increase HDL-C when LDL-C levels are adequately controlled while on a treatment with pravastatin 40 mg monotherapy **or on another moderate-intensity statin regimen**.

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 made 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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