



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Press Office

## Opinions on safety variations

Adopted at the CHMP meeting of 18-21 June 2012

Name of medicine	INN	Marketing authorisation holder	Scope
Avamys	fluticasone fluorate	Glaxo Group Ltd.	CHMP opinion recommending to update sections 4.4, 4.8 and 5.1 of the SmPC, as well as section 4 of the Product Leaflet with information on growth retardation and ocular changes in children.
Onbrez Breezhaler Oslif Breezhaler Hirobriz Breezhaler	indacaterol	Novartis Europharm Ltd.	CHMP opinion recommending to update the list and frequencies of adverse reactions in the SmPC section 4.8 based on additional data obtained post-marketing. A warning about hypersensitivity reactions has been added to the SmPC section 4.4.

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Pradaxa	dabigatran etexilate	Boehringer Ingelheim International GmbH	CHMP opinion recommending to update section 4.4 of the SmPC with a warning on the risk of using Pradaxa in patients with prosthetic valve disease based on additional data obtained post-marketing.
Volibris	ambrisentan	Glaxo Group Ltd.	CHMP opinion recommending to update section 4.3 and 5.1 of the SmPC, as well as section 2 of the Package Leaflet, with a contraindication for use of ambrisentan in patients with idiopathic pulmonary fibrosis (IPF) with or without secondary pulmonary hypertension. The CHMP endorsed a Direct Healthcare Professional Communication (DHPC) informing healthcare professionals of the revised recommendations.