



19 April 2012
EMA/CHMP/213035/2012
Press Office

Opinions on safety variations

Adopted at the CHMP meeting of 16-19 April 2012

Name of medicine	INN	Marketing authorisation holder	Scope
Micardis	telmisartan	Boehringer Ingelheim International GmbH	CHMP opinion to update section 4.4 of the SmPC to include a warning for diabetic patients treated with insulin or oral antidiabetics, and a warning on renin-angiotensin-aldosterone system (RAAS) blockage in patients with uncontrolled blood pressure. Section 4.8 of the SmPC has also been updated to include "cough", "somnolence" and "interstitial lung disease" as new side effects.
Pritor		Bayer Pharma AG	
Kinzalmono		Bayer Pharma AG	
MicardisPlus	telmisartan/hydrochlorothiazide	Boehringer Ingelheim International GmbH	CHMP opinion to update section 4.4 of the SmPC to include a warning for diabetic patients treated with insulin or oral antidiabetics, and a warning on renin-angiotensin-aldosterone system (RAAS) blockage in patients with uncontrolled blood pressure. Section 4.8 of the SmPC has also been updated
PritorPlus		Bayer Pharma AG	

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom

Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8669

E-mail info@ema.europa.eu **Website** www.ema.europa.eu

An agency of the European Union



Name of medicine	INN	Marketing authorisation holder	Scope
Kinzalkomb		Bayer Pharma AG	to include "cough", "somnolence" and "interstitial lung disease" as new side effects.
Onduarp Twynsta	telmisartan/ amlodipine	Boehringer Ingelheim International GmbH	CHMP opinion to update section 4.4 of the SmPC to include a warning for diabetic patients treated with insulin or oral antidiabetics, and a warning on renin-angiotensin-aldosterone system (RAAS) blockage in patients with uncontrolled blood pressure.
Xarelto	rivaroxaban	Bayer Pharma AG	<p>CHMP opinion to update sections 4.4, 5.1 and 5.2 of the SmPC to introduce information to prescribers and clarify that there is no need for monitoring of coagulation parameters during treatment with rivaroxaban in clinical routine. However, if clinically indicated, rivaroxaban levels can be measured by calibrated quantitative anti-Factor Xa tests.</p> <p>In addition, a new risk factor (bronchiectasis or history of pulmonary bleeding) for bleeding is introduced in SmPC section 4.4.</p>