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Press office

Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 25-28 January 2016

Name of medicine	INN	Scope
Anoro, Laventair	umeclidinium bromide/ vilanterol	PSUR assessment resulting in a variation to update section 4.8 of the SmPC to add the adverse reaction glaucoma with a frequency 'not known'. The package leaflet is updated accordingly.
Betmiga	mirabegron	PSUR assessment resulting in a variation to update section 4.8 of the SmPC to add the adverse reactions dizziness, headache, constipation and diarrhoea with a frequency 'common' and the adverse reaction hypertensive crisis with a frequency 'very rare'. The package leaflet is updated accordingly.
Iclusig	ponatinib	PSUR assessment resulting in a variation to update section 4.8 of the SmPC to add hypothyroidism with a frequency 'common'. The package leaflet is updated accordingly.
Jevtana	cabazitaxel	PSUR assessment resulting in a variation to update section 4.4 of the SmPC to add a warning on interstitial pneumonia/pneumonitis and interstitial lung disease and on bone marrow suppression, and to add the adverse reactions interstitial pneumonia/pneumonitis and interstitial lung disease to section 4.8 with a frequency 'not known'. The package leaflet is updated accordingly.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5550
Send a question via our website www.ema.europa.eu/contact

Name of medicine	INN	Scope
Mekinist	trametinib	PSUR assessment resulting in a variation to update sections 4.4 and 4.8 of the SmPC to add the risk of colitis and gastrointestinal perforation. The package leaflet is updated accordingly.
Pradaxa	dabigatran etexilate	CHMP opinion to update sections 4.4 and 4.9 of the SmPC to reflect the authorisation of a reversal agent (Praxbind, idarucizumab) for the anticoagulant effects of dabigatran.
Vidaza	azacitidine	PSUR assessment resulting in a variation to update sections 4.4 and 4.8 of the SmPC to add a warning on tumour lysis syndrome and the adverse reaction pyoderma gangrenosum with a frequency 'uncommon'. The package leaflet is updated accordingly.
Xydalba	dalbavancin	CHMP opinion to update section 4.2 with once-weekly dosing of 1500 mg dalbavancin as an alternative to two-dose regimen of 1000 mg and 500 one week apart based on the results from a phase III study. In addition, sections 4.8, 4.9, 5.1 and 5.2 have been revised to reflect study results. The package leaflet is updated accordingly.