



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 19-22 January 2015

Name of medicine	INN	Scope
Daliresp, Daxas, Libertek	roflumilast	PSUR assessment resulting in a CHMP opinion to update section 4.8 of the SmPC to include panic attack as a side effect with a frequency of "rare". The Package leaflet is updated accordingly.
Nevanac	nepafenac	PSUR assessment resulting in a CHMP opinion to update of section 4.8 of the SmPC to add corneal perforation as a new adverse drug reaction with a frequency "unknown" and update of section 4.4 of the SmPC to include a cross-reference to section 4.8. The Package leaflet is updated accordingly.
Rienso	ferumoxytol	PSUR procedure resulting in an update of section 4.4 of the SmPC to add a warning that elderly patients or patients with multiple co-morbidities who experience a serious hypersensitivity reaction may have more severe outcomes and to amend the warning on the interference with MRI.
Sprycel	dasatinib	PSUR assessment resulting in a CHMP opinion to update section 4.8 of the SmPC of dasatinib is to be updated to include Steven-Johnson syndrome as a side effect with frequency "not known".

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Victoza	liraglutide	PSUR assessment resulting in a CHMP opinion to update section 4.9 of the SmPC. During a PSUR procedure, a total of 84 cases (92 events) of overdose associated with the use of liraglutide were identified. The majority of overdose-related events were non-serious and included severe nausea, vomiting and diarrhoea. Based on this data, section 4.9 of the SmPC is to be updated.
Xeplion	paliperidone palmitate	PSUR assessment resulting in a CHMP opinion to update of section 4.2. During a PSUR procedure, a case of medication error with Xeplion was identified. In order to prevent further medication errors during the dosing monthly maintenance schedule, section 4.2 of the SmPC for Xeplion is to be updated in order to clarify that the third injection should be administered one month after the second injection and then monthly thereafter.
Betmiga	mirabegron	PSUR assessment resulting in a CHMP opinion to update section 4.8 of the SmPC to add nausea based on post marketing spontaneous reporting data. Taking into account the frequency of nausea observed in clinical trials (1.4%), the frequency for nausea is "common". The Package leaflet is updated accordingly.