



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 17-20 February 2014

Name of medicine	INN	Scope
Aloxi	palonosetron	PSUR assessment resulting in a CHMP opinion to update sections 4.4 and 4.5 of the SmPC to include a new warning on Serotonin Syndrome when administered either alone or in combination with other serotonergic agents
Betmiga	mirabegron	PSUR assessment resulting in a CHMP opinion to update section 4.4 of the SmPC to add a warning on urinary retention in patients with bladder outlet obstruction and patients taking concomitantly antimuscarinic medication for over active bladder
Elonva	corifollitropin alfa	CHMP opinion to update several SmPC sections, including moving 'polycystic ovarian syndrome (PCOS)' from section 4.4 to 4.3, to reflect recent medical information relevant to safety and efficacy and to provide more clarity and align with QRD template version 9.0.
SonoVue	sulphur hexafluoride fidaxomicin	CHMP opinion to move the contraindication 'use in patients with acute coronary syndrome or clinically unstable ischaemic cardiac disease' from section 4.3 to section 4.4 of the SmPC

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Bretaris Genuair, Eklima Genuair	acridinium bromide	PSUR assessment resulting in a CHMP opinion to update section 4.8 of the SmPC to include 'hypersensitivity', 'angioedema', 'rash' and 'pruritus' as Adverse Drug Reactions (with their corresponding frequency).
Siklos	hydroxycarbamide	PSUR assessment resulting in a CHMP opinion to update sections 4.6 and 4.8 of the SmPC to change the frequency of oligospermia and azoospermia from "very rare" to "very common".
Rebetol, Ribavirin Mylan, Ribavirin Teva, Ribavirin Teva Pharma BV	ribavirin	PSUR assessment resulting in a CHMP opinion to update section 4.8 of the SmPC to add the adverse reactions of tinnitus, hypotension, vasculitis cerebrovascular ischaemia and tongue pigmentation..
Pegasys	peginterferon alfa-2a	PSUR assessment resulting in a CHMP opinion to update section 4.4 of the SmPC to include information regarding glucose monitoring and section 4.8 to include the adverse reaction tongue pigmentation
Ketek	telithromycin	PSUR assessment resulting in a CHMP opinion to update sections 4.4. and 4.8 of the SmPC with additional clarification on the risk for severe and sudden visual reactions, addition of an interaction between telithromycin and sotalol in section 4.5 of the SmPC and addition of 'gamma-glutamyl transferase increase' with its corresponding frequency to the list of adverse reactions in section 4.8 of the SmPC.
Elaprase	idursulfase	PSUR assessment resulting in a CHMP opinion to update sections section 4.4 of the SmPC to revise the warning regarding patients with the complete deletion/large rearrangement genotype with a consequential update to section 4.8 of the SmPC.