



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Press Office

## Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 20-23 January 2014

Name of medicine	INN	Scope
alli	orlistat	CHMP opinion to update sections 4.4 and 4.5 of the Summary of Products Characteristics (SmPC) to introduce a warning in case of concomitant use of orlistat with antiretroviral agents due to a potential interaction based on an analysis of publications and post marketing reports. The section 4.5 is updated consequently. In addition, update of the package leaflet and outer packaging are introduced.
Samsca	tolvaptan	CHMP opinion to update sections 4.4 and 4.8 of the SmPC to include information on anaphylaxis, based on a case suspected to be due to tolvaptan identified from a search of the Marketing Authorisation Holder's pharmacovigilance database.
Viagra	sildenafil	CHMP opinion to update section 4.4 of the SmPC to include additional information regarding priapism and potential risk effects of exceeding the recommended dose for concomitant use of Viagra with other sildenafil containing products or other PDE5 inhibitors. The package leaflet is updated accordingly.

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Difficlor	fidaxomicin	PSUR assessment resulting in a CHMP opinion to update the SmPC section 4.4 with a statement that hypersensitivity reactions have been reported in some patients with a history of allergy to macrolides. The package leaflet is updated accordingly.
Neurpo/Leganto	rotigotine	CHMP opinion to update sections 4.4 and 4.8 of the SmPC in order to update the safety information on impulse control disorders and hypersensitivity in line with the updated company core data sheet.