



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 22-25 July 2013

Name of medicine	INN	Scope
CellCept	mycophenolate mofetil	CHMP opinion to update section 4.4 of the Summary of Product Characteristics (SmPC) in order to include a warning regarding hepatitis B and C reactivation associated with CellCept.
Invega	paliperidone	CHMP opinion to update sections 4.4 and 4.8 of the SmPC of risperidone and paliperidone-containing medicinal products to add a new adverse drug reaction of 'intraoperative floppy iris syndrome' (IFIS) and a related warning based on post-marketing reports, including reports from the literature.
Xeplion		
Risperdal film-coated tablets	risperidone	The CHMP endorsed a Direct Healthcare Professional Communication (DHPC) informing healthcare professionals of the revised recommendations.
Risperdal Consta		
Risperdal Oral Solution		

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Risperdal Quicklet		
Ganfort	bimatoprost/timolol	CHMP opinion to update section 4.8 of the SmPC to move the following ADRs from the tables for ADRs seen only with the individual components (timolol and bimatoprost) to the table for ADRs seen with GANFORT: Bronchospasm (predominantly in patients with pre-existing bronchospastic disease), dyspnea, eyelid retraction and dizziness. Additionally, the wording “Cases of corneal calcification have been reported very rarely in association with the use of phosphate containing eye drops in some patients with significantly damaged corneas” was added to section 4.8. The above-mentioned SmPC changes were reflected in the PL.
Invirase	saquinavir	CHMP opinion to update sections 4.2, 4.4 and 5.2 of the SmPC with warnings that an effective dose recommendation below thresholds of concern for QT and PR interval prolongation could not be established for paediatric patients. In addition, the description of the target population in the PL has been corrected in line with the SmPC.
Neulasta	pegfilgrastim	CHMP opinion to update sections 4.4 and 4.8 of the SmPC to add capillary leak syndrome as a new adverse drug reaction and include a related warning further to the assessment of a signal by the PRAC. The Package Leaflet is updated accordingly. The CHMP endorsed a DHPC informing healthcare professionals of the revised recommendations.
Neupogen	filgrastim	
Prezista	darunavir	CHMP opinion to update sections 4.4 and 4.8 of the SmPC with a new adverse reaction: drug rash with eosinophilia and systemic symptoms (DRESS) (frequency rare).
Tasigna	nilotinib	CHMP opinion to update sections 4.2 and 4.4 of the SmPC to recommend that the lipid profile be assessed before initiating treatment with Tasigna and monitored during treatment, as clinically indicated.
TOBI Podhaler	tobramycin	CHMP opinion to update section 4.8 of the SmPC with the adverse event “aphonia” in the system organ class (SOC) “Respiratory, thoracic and mediastinal disorders”, with the frequency grouping

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		"not known". Section 4 of the Package Leaflet was updated accordingly to include "loss of voice" under the frequency grouping "not known".
Zytiga	abiraterone	CHMP opinion to update sections 4.4 and 4.5 of the SmPC regarding interactions with inducers and inhibitors of CYP3A4. A new warning is added to section 4.4 against concomitant use of strong CYP3A4 inducers with abiraterone for fear of loss of efficacy.