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Press Office

Opinions on safety variations

Adopted at the CHMP meeting of 12-15 November 2012

Name of medicine	INN	Marketing authorisation holder	Scope
Arava Leflunomide Winthrop	leflunomide	Sanofi-aventis Deutschland GmbH	CHMP Opinion to update sections 4.4 and 4.8 of the SmPC to include a warning on occurrence of pustular psoriasis and worsening of psoriasis after the use of leflunomide, with possible consideration of treatment withdrawal, taking into account the patient's disease and past history. Further update was introduced in section 4.8 of the SmPC to include cutaneous lupus erythematosus. The product leaflet was updated accordingly.
Bondronat Bonviva Bondenza	ibandronic acid	Roche Registration Ltd.	CHMP Opinion to update SmPC section 4.8 to include 'anaphylaxis' as adverse drug reaction, including fatal, for intravenous and oral formulations. In addition, for intravenous formulations only, in SmPC section 4.4 a new warning was included regarding 'anaphylaxis'.

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Exelon Prometax	rivastigmine	Novartis Europharm Ltd.	CHMP Opinion to update SmPC section 4.4 of transdermal patches to include information on misuse and dosing errors resulting in overdose. Furthermore, information on special populations and precautionary information to avoid contact with eyes after handling transdermal patches were included. Section 4.8 of all formulations was updated to reflect safety findings of the study CENA713D2340.
Xeloda	capecitabine	Roche Registration Ltd.	CHMP Opinion to update SmPC sections 4.2 and 4.4 with new warnings and precautions regarding increased toxicity in patients with dihydro-pyrimidine dehydrogenase (DPD) deficiency. Moreover, section 4.8 was updated to include 'radiaton recall syndrome' as an Adverse Drug Reaction based on literature reports.
TachoSIL	human fibrinogen / human thrombin	Nycomed Austria GmbH	CHMP Opinion to include contraindication for intravascular application of TachoSil in SmPC sections 4.3 and 5.2 in line with the core SmPC for fibrin sealants. The summary of this opinion can be found on the European Medicines Agency's website under the 'November CHMP meeting highlights'.