15 December 2011
EMA/CHMP/941886/2011
Press Office

Opinions on safety variations

Adopted at the CHMP meeting of 12-15 December 2011

Name of medicine	INN	Marketing authorisation holder	Scope
Aclasta	zoledronic acid	Novartis Europharm Ltd.	CHMP opinion recommending to upgrade a warning to a contra-indication in patients with severe renal impairment (creatinine clearance less than 35ml/min). Sections 4.3, 4.4, 4.8 and 5.2 of the SmPC regarding renal impairment are amended accordingly.
Adenuric	febuxostat	Menarini International Operations Luxembourg S.A.	CHMP opinion recommending to amend sections 4.4 and 4.8 of the SmPC to add information on severe hypersensitivity reactions (including Stevens-Johnson syndrome and anaphylactic reaction) and hepatitis and jaundice.
Rilonacept Regeneron	rilonacept	Regeneron UK Limited	CHMP opinion recommending to add a warning in section 4.4 of the SmPC against rechallenge of rilonacept in patients who have experienced hypersensitivity reaction.
Teysuno	tegafur / gimeracil / oteracil	Taiho Pharma Europe Ltd.	CHMP opinion recommending to include in sections 4.2, 4.3, 4.4, 4.8, 5.1 and 5.2 of the SmPC information on the use in patients with severe renal impairment, in particular the current contraindication in severe renal

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			impairment has been changed to a warning that the administration of Teysuno is not recommended in severe renal impairment (renal clearance <30 ml/min) unless the benefits clearly outweigh the risks. A contraindication for patients with severe renal impairment who require dialysis remains.