



26 February 2016
EMA/76584/2016
Press office

Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 22-25 February 2016

Name of medicine	INN	Scope
Bonviva/Bondronat	ibandronic acid	PSUR assessment resulting in a variation to update information on Osteonecrosis of the jaw. In this PSUR the SmPC (sections 4.2, 4.4 and 4.8), Annex II and PL were updated to include the class information on osteonecrosis of the jaw (ONJ). The patient reminder card with relation to ONJ was recommended especially for parenteral formulations in order to optimise risk minimisation, in accordance to the class recommendation for all bisphosphonates.
Abilify, Abilify Maintena	aripiprazole	PSUR assessment resulting in a variation to update section 4.8 of the SmPC to add the adverse reaction hiccups with a frequency 'uncommon'.
Aluvia	lopinavir/ritonavir	Type II variation to update sections 4.4 and 4.5 of the SmPC in order to add information regarding the interaction between lopinavir/ritonavir and delamanid.



Name of medicine	INN	Scope
Exviera	dasabuvir	PSUR assessment resulting in a variation to update section 4.8 of the SmPC to add the adverse reaction angioedema with a frequency 'rare'.
Kaletra	lopinavir/ritonavir	Type II variation to update sections 4.4 and 4.5 of the SmPC in order to add information regarding the interaction between lopinavir/ritonavir and delamanid.
Norvir	ritonavir	Type II variation to update sections 4.4 and 4.5 of the SmPC in order to add information regarding the interactions between ritonavir and delamanid.
Nplate	romiplostim	PSUR assessment resulting in a variation to update section 6.6 of the SmPC to add a table to clarify the issue of vial overfill.
Picato	ingenol mebutate	PSUR assessment resulting in a variation to update sections 4.4 and 4.8 of the SmPC to add the adverse reactions pigmentation change, hypersensitivity (including angioedema), chemical conjunctivitis and corneal burn with a frequency uncommon and to add a warning on chemical conjunctivitis and corneal burn after accidental eye exposure.
Viekirax	ombitasvir/paritaprevir/ritonavir	PSUR assessment resulting in a variation to update section 4.8 of the SmPC to add the adverse reaction angioedema with a frequency 'rare'.
Zaltrap	aflibercept	PSUR assessment resulting in a variation to update sections 4.4 and 4.8 of the SmPC to revise the warning on proteinuria, to add a warning on osteonecrosis of the jaw and to add the adverse effect osteonecrosis of the jaw with a frequency 'uncommon'.
Tepadina	thiotepa	Type II variation to update section 4.8 of the SmPC to add information regarding cases of leukoencephalopathy that have been observed following treatment with thiotepa in adult and paediatric patients with multiple previous chemotherapies, including methotrexate and radiotherapy. Some cases had a fatal outcome.
Imbruvica	ibrutinib	Type II variation to update sections 4.8 and 4.9 of the SmPC with information on hepatic failure and hepatotoxicity.