



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 April 2015

| Name of medicine | INN | Scope |
|------------------|--------------------|---|
| Aubagio | terifluomide | PSUR procedure resulting in an update of sections 4.4 and 4.8 of the SmPC with information on severe skin reactions, including Steven Johnson syndrome, reported with the medicine. |
| Esmya | ulipristal acetate | Extension of indication to include the use in intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. In that context, section 4.4 of the SmPC has been updated with recommendations for periodic monitoring of the endometrium and information on the management of altered bleeding (inter-menstrual bleeding) and hyperplasia (with and without atypia). |
| Prolia | denosumab | PSUR procedure resulting in an update of sections 4.2, 4.4 and 4.8 of the SmPC to reflect the current knowledge on osteonecrosis of the jaw (ONJ). Annex II is updated to reflect the introduction of a patient reminder card containing information on the risk of ONJ. |

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5550

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| Rasilez, Rasilamlo, Rasilez HCT | aliskiren, aliskiren/ amlodipine, aliskiren/ hydrochlorothiazide | PSUR procedure resulting in an update of section 4.8 of the SmPC to add the adverse reaction hyponatremia with a frequency "not known" and the adverse reaction dyspnoea with a frequency "not known". For the fixed dose combination products affected by this procedure, in case the event occurred with unknown frequency for one of the components, and a known frequency was assigned for another component or a combination, the event is only listed once under the already known frequency and an index is added to indicate the component with which the event occurs. The Package leaflet is updated accordingly. |
| SonoVue | sulphur hexafluoride | PSUR procedure resulting in an update of sections 4.3 and 4.6 of the SmPC to remove the pregnancy and lactation contraindication and to further align the wording in the two sections, and also resulting in the inclusion of information on the rapid elimination of SonoVue from the body. Section 4.8 is updated to improve readability and amend the frequencies of some adverse reactions. |
| Synflorix | pneumococcal polysaccharide conjugate vaccine | Type II variation to update the section 4.4 of the SmPC with information on clinical data indicating that paracetamol administered before or after vaccination might reduce the immune response to Synflorix. |
| Tyverb | lapatinib | PSUR procedure resulting in an update of sections 4.4 and 4.8 of the SmPC to add serious cutaneous reactions as an adverse event with a frequency "unknown". |
| Xgeva | denosumab | PSUR procedure resulting in an update of sections 4.2, 4.4 and 4.8 of the SmPC to reflect the current knowledge on osteonecrosis of the jaw (ONJ). Section 4.3 is updated to contraindicate starting in patients while there are any unhealed lesions in the mouth from dental or oral surgery. Annex II is updated to reflect the introduction of a patient reminder card containing information on the risk of ONJ. |
| Yervoy | ipilimumab | PSUR procedure resulting in an update of section 4.4 of the SmPC to warn against immune-related skin adverse reactions in patients on a prior cancer immune stimulatory therapy and of new cases of 'Drug Reaction (rash) with Eosinophilia and Systemic Symptoms' (DRESS syndrome). In addition, section 4.8 of the SmPC has been updated to include DRESS syndrome with a frequency of rare. The package leaflet has been updated accordingly. |
| Yondelis | trabectedin | PSUR procedure resulting in an update of section 4.2 of the SmPC to include a reference to section 4.4 which recommends that health care professionals use central venous access. |

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| Zometa, Zoledronic acid Medac and nationally authorised medicines | zoledronic acid | PSUSA procedure resulting in an update of sections 4.2, 4.4 and 4.8 of the SmPC to reflect the current knowledge on osteonecrosis of the jaw (ONJ). Annex II is updated to reflect the introduction of a patient reminder card containing information on the risk of ONJ. |