



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 March 2012
EMA/CHMP/162997/2012
Press Office

Opinions on safety variations

Adopted at the CHMP meeting of 12-15 March 2012

| Name of medicine | INN | Marketing authorisation holder | Scope |
|------------------|------------|-----------------------------------|---|
| Abraxane | paclitaxel | Celgene Europe Ltd. | CHMP opinion recommending changes to sections 4.4 and 4.8 of the SmPC to include information on interstitial pneumonitis in relation to off-label use. |
| Samsca | tolvaptan | Otsuka Pharmaceutical Europe Ltd. | CHMP opinion recommending changes to sections 4.2, 4.4, 4.5 and 4.8 of the SmPC to include recommendations on monitoring fluid and electrolyte status and warnings on concomitant use with other treatments for hyponatraemia or other medicinal products that increase serum sodium concentration. The CHMP has endorsed a Direct Healthcare Professional Communication (DHPC) informing healthcare professionals of the revised recommendations. |

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