

**Prescription only proton pump inhibitors (omeprazole  
esomeprazole/naproxen, omeprazole/ketoprofen, esomeprazole, lansoprazole,  
pantoprazole, rabeprazole) and risk of fractures of the hip, wrist and spine**

**Final SmPC and PL wording agreed by PhVWP March 2012**

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## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **Section 4.4**

Proton pump inhibitors, especially if used in high doses and over long durations (>1 year), may modestly increase the risk of hip, wrist and spine fracture, predominantly in the elderly or in presence of other recognised risk factors. Observational studies suggest that proton pump inhibitors may increase the overall risk of fracture by 10–40%. Some of this increase may be due to other risk factors. Patients at risk of osteoporosis should receive care according to current clinical guidelines and they should have an adequate intake of vitamin D and calcium.

### **Section 4.8**

Musculoskeletal disorders

Frequency (uncommon): Fracture of the hip, wrist or spine (see section 4.4)

## **PACKAGE LEAFLET**

Taking a proton pump inhibitor like (PRODUCT), especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).