

## **SSRIs and TCAs and the risk of bone fractures**

**Final SPC and PL wording agreed by the PhVWP in March 2010**

*Doc. Ref.: CMDh/PhVWP/020/2010  
March 2010*

### **SUMMARY OF PRODUCT CHARACTERISTICS**

#### **Section 4.8 for all SSRIs and TCAs**

##### *Class effects*

Epidemiological studies, mainly conducted in patients 50 years of age and older, show an increased risk of bone fractures in patients receiving SSRIs and TCAs. The mechanism leading to this risk is unknown.

### **PACKAGE LEAFLET**

An increased risk of bone fractures has been observed in patients taking this type of medicines.