

# **Conventional (Typical) Antipsychotics and increased mortality in elderly people with Dementia**

**Final SPC and PL wording agreed by PhVWP October 2009**

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## **SUMMARY OF PRODUCT CHARACTERISTICS**

### *Section 4.4 - Special warnings and precautions for use*

#### **Increased Mortality in Elderly people with Dementia**

Data from two large observational studies showed that elderly people with dementia who are treated with antipsychotics are at a small increased risk of death compared with those who are not treated. There are insufficient data to give a firm estimate of the precise magnitude of the risk and the cause of the increased risk is not known.

{Invented name} is not licensed for the treatment of dementia-related behavioural disturbances.

## **PACKAGE LEAFLET**

### *Section 4 - Possible side effects*

- In elderly people with dementia, a small increase in the number of deaths has been reported for patients taking antipsychotics compared with those not receiving antipsychotics