

## **Sikkerhetsoppdatering**

### **Konvensjonelle antipsykotika og økt dødelighet hos eldre pasienter med demens**

Mai 2010

#### **Tekst til preparatomtale**

#### **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.

#### **Tekst til pakningsvedlegg**

#### **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