

**SPC Wording for risperidone**  
in relation to:  
**concomitant use with furosemide and increased mortality in elderly patients with dementia**  
as agreed following the PhVWP in September 2005

**Section 4.4**

**Elderly Patients with Dementia**

Elderly patients with dementia treated with atypical antipsychotic drugs had an increased mortality compared to placebo in a meta-analysis of 17 controlled trials of atypical antipsychotic drugs, including Risperdal. In placebo-controlled trials with Risperdal in this population, the incidence of mortality was 4.0% for Risperdal –treated patients compared to 3.1% for placebo-treated patients. The mean age (range) of patients who died was 86 years (67-100).

In these trials treatment with furosemide plus risperidone was associated with a higher incidence of mortality compared to treatment with risperidone or furosemide alone, however, the mechanism for an interaction is unclear. Concomitant use of risperidone with other diuretics (*mainly thiazide diuretics used in low dose*) was not associated with similar findings.

No consistent pattern for cause of death observed. Nevertheless caution should be exercised and the risks and benefits of the combination of risperidone and furosemide or co-medication with other potent diuretics considered prior to the decision to use. Irrespective of treatment, dehydration was an overall risk factor for mortality and should therefore be carefully avoided in elderly patients with dementia.