

SPC Wording for Antipsychotics

in relation to:

Risk of cerebrovascular accidents (CVA), in particular when used in dementia patients.

as agreed following the PhVWP in September 2005

Section 4.4

An approximately 3-fold increased risk of cerebrovascular adverse events have been seen in randomised placebo controlled clinical trials in the dementia population with some atypical antipsychotics. The mechanism for this increased risk is not known. An increased risk cannot be excluded for other antipsychotics or other patient populations. <...> should be used with caution in patients with risk factors for stroke.