

Antipsychotics and risk of venous thromboembolism (VTE)

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

Cases of venous thromboembolism (VTE) have been reported with antipsychotic drugs. Since patients treated with antipsychotics often present with acquired risk factors for VTE, all possible risk factors for VTE should be identified before and during treatment with {Invented name} and preventive measures undertaken

Section 4.8 Undesirable effects

If no cases with specific product

Cases of venous thromboembolism, including cases of pulmonary embolism and cases of deep vein thrombosis have been reported with antipsychotic drugs- Frequency unknown

If cases with specific product

Venous thromboembolism should be listed as appropriate

PACKAGE LEAFLET

Section 2 - Take special care with {Invented name}:

If you or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots

Section 4 - Possible side effects

Blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately