

## **Sikkerhetsoppdatering**

### **Antipsykotika og risiko for venøs tromboembolisme**

Mai 2010

#### **Tekst til preparatomtale**

#### **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

#### **Tekst til pakningsvedlegg**

#### **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