

**Insulin Products and Risk of Cardiac Failure  
with Concomitant Use of Pioglitazone**

**Final SmPC wording agreed by the PhVWP in February 2011**

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**SUMMARY OF PRODUCT CHARACTERISTICS**

SmPC section 4.4 Special Warnings and Precautions for Use

Combination of <insulin product> with pioglitazone:

Cases of cardiac failure have been reported when thiazolidinediones are used in combination with insulin, especially in patients with risk factors for development of cardiac heart failure. This should be kept in mind if treatment with the combination of pioglitazone and <insulin product> is considered. If the combination is used, patients should be observed for signs and symptoms of heart failure, weight gain and oedema. Pioglitazone should be discontinued, if any deterioration in cardiac symptoms occurs.