

**Key Elements for SPC Wording for
Labour Inducers (dinoprostone and oxytocin)
with regard to the Risk of Disseminated Intravascular Coagulation (DIC)
agreed by the PhVWP in October 2003**

Section 4.4 Special warnings and precautions for use

- Pharmacological induction of labour with dinoprostone or oxytocin is thought to increase the risk of post-partum disseminated intravascular coagulation (DIC), a very rare condition.
- This increased risk may be more relevant in women aged 35 years or older, women with complications during gestation and women with a gestational age over 40 weeks.
- In these women, use of *<name of product>* should be undertaken with caution and physicians should be alert for signs of DIC (i.e. fibrinolysis).

Section 4.8 Undesirable effects

Rare: Disseminated intravascular coagulation (see Section 4.4).