



## Uniferon Best Practice Recommendation

### Pharmacovigilant anaemia care

Each national health care system has a pharmacovigilance system associated with the prescription and administration of medicines in humans and animals, which ensures a satisfactory handling of adverse events in compliance with local laws and guidelines.

Pharmacovigilance reporting is of high importance to quality care and thus to Pharmacosmos – Committed to Quality.

Pharmacosmos has the overall responsibility for maintaining a highly compliant and skilled safety surveillance of Uniferon. Pharmacosmos has organised worldwide reporting of adverse events via Uniferon partners and in compliance with local legislation. In parallel, Pharmacosmos systematically reviews the worldwide scientific literature for the product and is responsible for signal detection.

#### Adverse reactions to Uniferon

The overall reported frequency of adverse events in treatment with Uniferon is very low. Periodic Safety Update Report (PSUR) from 2009-2013 had a reporting rate of 0.00003%.

The following types of adverse events are common to administration of parental iron, however, have only been reported in treatment with Uniferon in very few cases.

- Transient discoloration and calcifications at the injection site
- Hypersensitivity reactions
- Piglet death attributed to an increased susceptibility to infection due to temporary blocking of the reticuloendothelial system
- Death in piglets due to underlying genetic factors or deficiency of vitamin E and/or selenium

In case of an adverse event please inform your local Uniferon Partner without undue delay.

Sincerely  
The Uniferon Team

