CLARIFICATIONS AND ADDITIONS TO THE CONTENT OF THE SUMMARY OF PRODUCT CHARACTERISTICS FOR ALL IV IRON PRODUCTS

The individual SmPCs for all IV iron products have been strengthened with regards to the risk of serious hypersensitivity reactions. The following text outlines the updates, clarifications, and additions to the SmPC only. This is not a full SmPC.

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

[…]

4.2 Posology and method of administration

[…]

Monitor carefully patients for signs and symptoms of hypersensitivity reactions during and following each administration of {invented name}.

{Invented name} should only be administered when staff trained to evaluate and manage anaphylactic reactions is immediately available, in an environment where full resuscitation facilities can be assured. The patient should be observed for adverse effects for at least 30 minutes following each {invented name} injection (see section 4.4).

[…]

[All references to the recommendation for an initial test dose before the administration of the first dose to a new patient will be removed in section 4.2 and in any other sections of the SmPC where applicable. The current information on subsequent doses/administration of the product, including for example slower initial rate of administration, will remain unchanged]

[…]

4.3. Contraindications

[…]

- Hypersensitivity to the active substance, to {invented name} or any of its excipients listed in section 6.1.
- Known serious hypersensitivity to other parenteral iron products.

[…]

4.4 Special warnings and precautions for use

[…]

Parenterally administered iron preparations can cause hypersensitivity reactions including serious and potentially fatal anaphylactic/anaphylactoid reactions. Hypersensitivity reactions have also been reported after previously uneventful doses of parenteral iron complexes.

The risk is enhanced for patients with known allergies including drug allergies, including patients with a history of severe asthma, eczema or other atopic allergy.
There is also an increased risk of hypersensitivity reactions to parenteral iron complexes in patients with immune or inflammatory conditions (e.g. systemic lupus erythematosus, rheumatoid arthritis).

{Invented name} should only be administered when staff trained to evaluate and manage anaphylactic reactions is immediately available, in an environment where full resuscitation facilities can be assured. Each patient should be observed for adverse effects for at least 30 minutes following each {invented name} injection. If hypersensitivity reactions or signs of intolerance occur during administration, the treatment must be stopped immediately. Facilities for cardio respiratory resuscitation and equipment for handling acute anaphylactic/anaphylactoid reactions should be available, including an injectable 1:1000 adrenaline solution. Additional treatment with antihistamines and/or corticosteroids should be given as appropriate.

[…]

4.6 Fertility, pregnancy and lactation

[…]

There are no adequate and well-controlled trials of {invented name} in pregnant women. A careful risk/benefit evaluation is therefore required before use during pregnancy and {invented name} should not be used during pregnancy unless clearly necessary (see section 4.4).

Iron deficiency anaemia occurring in the first trimester of pregnancy can in many cases be treated with oral iron. Treatment with {invented name} should be confined to second and third trimester if the benefit is judged to outweigh the potential risk for both the mother and the foetus.

[…]

4.8 Undesirable effects

[…]

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions {via the national reporting system listed in Appendix V*}.

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