Annex III

Amendments to relevant sections of the summary of product characteristics and package leaflets

Note:

This summary of product characteristics, labelling and package leaflet is the outcome of the referral procedure.

The product information may be subsequently updated by the Member State competent authorities, in liaison with the Reference Member State, as appropriate, in accordance with the procedures laid down in Chapter 4 of Title III of Directive 2001/83/EC.

SUMMARY OF PRODUCT CHARACTERISTICS

[this wording should be inserted]

▼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

[the wording below should be inserted in the relevant section]
[…]

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 should 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, should remain unchanged]

[…]

4.3. Contraindications

[the wording below should be inserted in the relevant section]

[…]

- 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

[the wording below should be inserted in the relevant section]

[…]

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

[the wording below should be inserted in the relevant section]

[…]

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

[the wording below should be inserted in the relevant section]

[…]

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*}.

*[*For the printed material, please refer to the guidance of the annotated QRD template.]*

[…]

PACKAGE LEAFLET

[This wording should be inserted]

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

[…]

2. What you need to know before you receive {invented name}

[the wording below should be inserted in the relevant section]

[…]

You must not receive {invented name}:
- if you are allergic (hypersensitive) to the product or any of the other ingredients of this medicine (listed in section 6).
- if you have experienced serious allergic (hypersensitive) reactions to other injectable iron preparations.

Warnings and precautions
Talk to your doctor or nurse before receiving {invented name}:
- if you have a history of medicine allergy
- if you have systemic lupus erythematosus
- if you have rheumatoid arthritis
- if you have severe asthma, eczema or other allergies

How {invented name} is given

Your doctor or nurse will administer {invented name} by {route of administration defined in posology section of SmPC}; the {invented name} will be administered in a structure where immunoallergic events can receive appropriate and prompt treatment.

You will be observed for at least 30 minutes by your doctor or nurse after each administration.

Pregnancy

{invented name} has not been tested in pregnant women. It is important to tell your doctor if you are pregnant, think you may be pregnant, or are planning to have a baby.
If you become pregnant during treatment, you must ask your doctor for advice.
Your doctor will decide whether or not you should be given this medicine.

Breast-feeding

If you are breast-feeding, ask your doctor for advice before you are given {invented name}.

4. Possible side effects

[the wording below should be inserted in the relevant section]
[…]

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via {the national reporting system listed in Appendix V}*. By reporting side effects you can help provide more information on the safety of this medicine.

*[*For the printed material, please refer to the guidance of the annotated QRD template.]*