



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 28-31 October 2019 PRAC

The product information wording in this document is extracted from the document entitled 'PRAC recommendations on signals' which contains the whole text of the PRAC recommendations for product information update, as well as some general guidance on the handling of signals. It can be found [here](#) (in English only).

New text to be added to the product information is underlined. Current text to be deleted is ~~struck through~~.

1. Iron sucrose; iron carboxymaltose; iron isomaltoside; iron dextran; sodium ferric gluconate – Arteriospasm coronary (EPITT no 19408)

Summary of product characteristics

4.4. Special warnings and precautions for use

Hypersensitivity reactions

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. There have been reports of hypersensitivity reactions which progressed to Kounis syndrome (acute allergic coronary arteriospasm that can result in myocardial infarction, see section 4.8).

4.8. Undesirable effects

Cardiac disorders

Frequency 'Not known': Kounis syndrome

¹ Intended publication date. The actual publication date can be checked on the webpage dedicated to [PRAC recommendations on safety signals](#).



Package leaflet

4. Possible side effects

Allergic reactions

Tell your doctor immediately if you experience any of the following signs and symptoms that may indicate a serious allergic reaction And chest pain which can be a sign of a potentially serious allergic reaction called Kounis syndrome.