


## ***VI.2 Elements for a public summary***

### ***VI.2.1 Overview of disease epidemiology***

#### Iron deficiency

Iron deficiency is the most common nutritional disorder affecting about 20-25% of the world's population, predominantly children and women. (5) (6) About two billion people are iron-deficient, with half of them manifesting clinical signs of anaemia (a decrease in the amount of red blood cells in the blood). Anaemia can result from non-nutritional factors, such as haemorrhage, infection, chronic disease states, or drug toxicity, and from nutritional ones, including deficiencies of iron, certain vitamins, copper, and protein. (6) (7) (8) Iron deficiency is more likely in women of reproductive age because of menstrual blood loss (approximately 4-8% of premenopausal women are iron deficient). However, extremes of blood loss such as regular blood donation, diets of low bioavailability and the challenges of pregnancy all markedly increase the risk of iron deficiency. (6) In men and postmenopausal women, iron

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deficiency is uncommon in the absence of bleeding. In certain geographic areas, intestinal parasites worsen the iron deficiency because of blood loss from the gastrointestinal tract. Race probably has no significant effect upon the occurrence of iron deficiency anemia. (9)

#### Iron deficiency during pregnancy


Anemia is the most frequent derailment of physiology in the world throughout the life of a woman, with pregnant women at particular risk. (10) The prevalence of anaemia in pregnancy varies considerably because of differences in socioeconomic conditions, lifestyles and health-seeking behaviours across different cultures. Iron deficiency, the most common cause of anaemia in pregnancy worldwide, can be mild, moderate or severe. Severe anaemia can have very serious consequences for mothers and babies. (11) The high prevalence of iron and other micronutrient deficiencies among women during pregnancy in developing countries is of concern and maternal anaemia is still a cause of considerable perinatal morbidity and mortality. (24) (12) World Health Organization (WHO) data show that iron deficiency anaemia in pregnancy is a significant problem throughout the world, affecting nearly half of all pregnant women in the world: 52% in developing countries compared with 23% in the developed world. (12) (25)

#### ***VI.2.2 Summary of treatment benefits***

Iron is an essential element for almost all living organisms as it participates in a wide variety of body processes, including oxygen transport and genetic material synthesis. (26)

Iron supplementation has shown to improve iron status in efficacy trials: there is substantial evidence that treatment of iron deficiency anaemia improves several important human functions. (27) Therefore, iron supplementation has been used in patients and groups at high risk of deficiency and/or in whom adequate dietary intake is unlikely to be achieved, as well as in therapy for those with presumed or established iron-deficiency anaemia. Oral administration is the route of choice for iron therapy in most patients and for iron supplementation. (2)

World Health Organization (WHO) and many other advisory groups recommend universal iron supplementation for all pregnant women, regardless of their iron status. (27) During the first and second trimester of pregnancy, iron-deficiency anaemia is associated with a two-fold

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increased risk of premature delivery and a three-fold increased risk of a low-birthweight delivery. Iron supplementation during pregnancy has been shown to decrease the incidence of anaemia. Therefore, primary prevention of iron deficiency in pregnant women requires adequate dietary iron intake and iron supplementation. Although conclusive evidence of the benefits of routine iron supplementation for all women currently is lacking, routine prophylactic iron supplementation currently is recommended for all pregnant women because a large proportion of such women experience difficulty in maintaining iron stores during pregnancy. In conclusion, iron-deficiency anaemia during pregnancy is associated with adverse outcomes, and such supplementation during pregnancy is not associated with important health risks. (2)


### ***VI.2.3 Unknowns relating to treatments benefits***

This section is not applicable.

### ***VI.2.4 Summary of safety concerns***

#### **Important potential risk**

<b>Risk</b>	<b>What is known (including reason why it is considered a potential risk)</b>
<b>Poisoning</b>	<p>Iron-based preparations can cause poisoning, especially in children; but there were no reported cases of accidental poisoning with fatal consequences. The potential severity of iron poisoning is based on the amount of elemental iron ingested. Particular attention should be paid in case of iron supplementation. (19) (22)</p> <p>In cases of overdosage neither intoxication nor iron overload have been reported to date because the iron from the active substance is not present in the gastro-intestinal tract as free iron. (2) (19) (22)</p>

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### ***VI.2.5 Summary of risk minimisation measures by safety concern***

All medicines have a SmPC which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package information leaflet (PIL). The measures in these documents are known as routine risk minimisation measures.

This medicine has no additional risk minimisation measures.

### ***VI.2.6. Planned post authorisation development plan (if applicable)***

This section is not applicable.

### ***VI.2.7. Summary of changes to the risk management plan over time***

<b>Version</b>	<b>Date</b>	<b>Safety Concerns</b>	<b>Comment</b>
1.0	18-07-2016	N/A	First version of the RMP
2.0	02-03-2017	N/A	Following D105 assessment report