



PRODUCT SPECIFICATION SHEET

Iron 60 mg tabs/PAC-100

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Material No: S1550010
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1. General Description

Iron 60mg (as Ferrous fumarate, gluconate, or sulfate) tablets, bottle of 100

2. Technical Specifications

Coated tablets containing Ferrous salt (fumarate, gluconate or sulfate) equivalent to 60mg elemental iron in a bottle of 100 tablets.

Acceptable pharmacopoeias

- British Pharmacopoeia (BP)
- United States Pharmacopoeia (USP)
- European Pharmacopoeia (Ph.Eur.)
- International Pharmacopoeia (Ph.Int)

3. Therapeutic Class

Antianaemia

4. Standard Shelf life

36 months

5. Stability Data requirements

Zone IVb as per ICH guidelines

6. Packaging and Labelling

A Patient Information Leaflet is provided with each pack.

Refer to *UNICEF Technical requirements for pharmaceutical products* [5 \(unicef.org\)](https://www.unicef.org/5)

Child-Proof Packaging: Child resistant cap on each pack/bottle is preferred

7. Guidelines for Use

As per the WHO guidelines

1. WHO recommendations on antenatal care for a positive pregnancy experience. World Health Organization 2016
<http://apps.who.int/iris/bitstream/10665/250796/1/9789241549912-eng.pdf?ua=1>
2. Guidelines for the Use of Iron Supplements to Prevent and Treat Iron Deficiency Anemia (motherchildnutrition.org)

8. Storage and Transportation

Do not store or transport above 30 degrees

9. Material safety data sheet information (MSDS): Required

Useful Resources

1. Minimum stability testing reporting requirements (guidance) for stability reports- Nutritional supplements (Tablets & oral solutions)
2. Interagency finished pharmaceutical product questionnaire
3. Technical questionnaire for pharmaceutical manufacturers
4. Technical Requirements for Pharmaceutical and Nutrition Products

FOR MORE INFORMATION

CPHHQ-SD- Nutrition Supplies sd.nutritionssupplies@unicef.org

[Technical resources for nutrition products | UNICEF Supply Division](#)