

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ferrograd C 325mg/500mg Prolonged release Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Dried Ferrous Sulphate 325 mg (elemental iron 105 mg)
Vitamin C 500 mg (as sodium ascorbate)

Excipient(s) with known effect
Dye Red Ponceau 4R Lake (E124)

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Prolonged release tablet.

Product imported from the UK
Ovoid, biconvex, red film-coated tablets.

4 CLINICAL PARTICULARS

As per PA1235/002/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1235/002/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methylacrylate methylmethacrylate copolymer
Magnesium stearate
Povidone
Macrogol 400
Macrogol 8000
Maize starch
Purified talc
Ethylcellulose
Hypromellose
Titanium Dioxide (E171)
Dye Red Ponceau 4R Lake (E124)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the blister strips and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package in order to protect from light and moisture.

6.5 Nature and contents of container

Overlabelled cardboard outer containing blister strips. Each blister strip contains 15 tablets.
Pack size: 30

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Ltd
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/141/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th December 2010

10 DATE OF REVISION OF THE TEXT

May 2018