# Summary of Product Characteristics

▼ 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.

## 1 NAME OF THE MEDICINAL PRODUCT

CosmoFer 50 mg/ml solution for infusion and injection

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 50 mg iron (III) as iron (III)-hydroxide dextran complex.

Each ampoule of 2 ml contains 100 mg iron (III) as iron (III)-hydroxide dextran complex.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Solution for injection/infusion

*Product imported from Bulgaria*
A dark brown solution

## 4 CLINICAL PARTICULARS

As per PA0982/001/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0982/001/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Water for injections
Sodium hydroxide (pH adjuster)
Hydrochloric acid (pH adjuster)

### 6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

### 6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the ampoules and outer package of the product on the market in the country of origin.
From a microbiological point of view, the product should be used immediately.
After dilution:
Chemical and physical in-use stability has been demonstrated for 24 hours at 25 °C.
From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.

**6.4 Special precautions for storage**

This medicine does not require any special storage conditions.

Do not freeze.

For storage conditions after dilution of the medicinal product, see section 6.3.

**6.5 Nature and contents of container**

CosmoFer is contained in clear glass ampoules.

Pack size: 5 ampoules

**6.6 Special precautions for disposal and other handling**

Inspect ampoules visually for sediment and damage before use. Use only those containing sediment-free, homogeneous solution.
CosmoFer is for single use only.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.
CosmoFer must only be mixed with 0.9% sodium chloride or 5% glucose solution. No other intravenous dilution solutions or therapeutic agents should be used.
The reconstituted solution for infusion and injection is to be visually inspected prior to use.
Only clear solutions without particles should be used.

**7 PARALLEL PRODUCT AUTHORISATION HOLDER**

Originalis B.V.
Joop Geesinkweg 901
1114 AB Amsterdam-Duivendrecht
Netherlands

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA2306/021/001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 18th October 2019

**10 DATE OF REVISION OF THE TEXT**