# SUMMARY OF PRODUCT CHARACTERISTICS

## FERRODEX CAPSULES

# 1. Name of the medicinal product

Ferrodex Capsules

# 2. Qualitative and quantitative composition

Each capsule of FERRODEX contains Iron (III) Polymaltose (equivalent to elemental Iron) 100 mg, Folic acid 2.5 mg, Pyridoxine HCl 2 mg, Cyanocobalamine 5 mcg, Zinc sulphate 20 mg and Ascorbic acid 155 mg

For a full list of excipients, see section 6.1.

# 3. Pharmaceutical form

Capsules

# 4. Clinical particulars

### 4.1 Therapeutic indications

Ferrodex Capsules is indicated for the treatment of iron deficiency in the following indications:

- anaemia associated with poor nutrition, piles and generalized weakness
- iron deficiency anaemia due to chronic blood loss
- Increase iron demand during pregnancy and lactation.

Ferrodex capsules contains vitamins supplement and folic acid for prevention or correction of disorders due to a vitamin or mineral imbalance or deficiency diet during pregnancy and lactation.

### 4.2 Posology and method of administration

*Posology*

*Adults* and children over 12 years

One capsule daily taken with or after meals

Method of administration

Orally with water

### 4.3 Contraindications

The use of Ferrodex capsule is contraindicated in the following conditions:

• Hypersensitivity to the active substances, to Ferrodex capsule or any of its excipients listed in section 6.1

• Anaemia not caused by iron deficiency

• Evidence of iron overload or hereditary disturbances in utilisation of iron.

### 4.4 Special warnings and precautions for use

The risk of hypersensitivity reactions is enhanced for patients with known allergies including drug allergies, including patients with a history of severe asthma, eczema or other atopic allergy.

If hypersensitivity reactions or signs of intolerance occur during administration, the treatment must be stopped immediately. In patients with liver dysfunction, iron should only be administered after careful risk/benefit assessment. Iron administration should be avoided in patients with hepatic dysfunction where iron overload is a precipitating factor, in particular Porphyria Cutanea Tarda (PCT). Careful monitoring of iron status is recommended to avoid iron overload.

Iron should be used with caution in the case of acute or chronic infection. It is recommended that the administration of Ferrodex capsule is stopped in patients with bacteraemia. In patients with chronic infection, a risk/benefit evaluation should be performed.

The additional requirements for folic acid should be borne in mind when treatment with iron is carried out during pregnancy. In cases of anaemia due to infection or malignancy, the substituted iron is stored in the reticulo-endothelial system, from which it is mobilised and utilised only after curing the primary disease. Caution is advised in individuals with a family history of haemochromatosis or an iron overload syndrome. It should be noted that these conditions may be under diagnosed.

### 4.5 Interaction with other medicinal products and other forms of interaction

Cholestyramine and colestipol may decrease the absorption of fat-soluble vitamins. Magnesium trisilicate and tetracycline reduce the absorption of oral iron. Oral iron reduces the absorption of certain 4-quinolines eg ciprofloxacin and norfloxacin. Absorption of vitamins B12 in the GIT is reduced by neomycin, histamine, H12 antagonists and colchicine. Folic acid occasionally reduces plasma- phenytoin concentrates
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### 4.6 Fertility, pregnancy and lactation

Pregnancy

**Pregnancy Category A**

Reproduction studies in animals did not show any foetal risk. Controlled studies in pregnant women after the first trimester have not shown any undesirable effects on mother and neonates. There is no evidence of a risk during the first trimester and a negative influence on the foetus is unlikely.

Iron deficiency anaemia occurring in the first trimester of pregnancy can in many cases be treated with oral iron.

Breast-feeding

Preclinical data do not indicate direct or indirect harmful effects to the nursing child. In lactating rats treated with Fe-labelled iron sucrose, low secretion of iron into the milk and transfer of iron into the offspring was observed. Non metabolised iron sucrose is unlikely to pass into the mother's milk.

Breast milk naturally contains iron bound to lactoferrin. It is not known how much iron from the complex is passed into breast milk. The administration of Ferrodex capsule is unlikely to cause undesirable effects to the nursed child. During pregnancy and lactation Ferrodex capsule should be used only after consulting a physician.

Fertility

No effects of iron sucrose treatment were observed on fertility and mating performance in rats.

### 4.7 Effects on ability to drive and use machines

No known symptoms of dizziness and hence does not affect driving or use of machinery.

### 4.8 Undesirable effects

**Very rarely gastro-intestinal discomfort, vomiting, constipation or diarrhoea can occur.**
**A dark colouration of the stool is of no clinical significance.**

The most important serious adverse drug reactions associated with Ferrodex capsule are hypersensitivity reactions, which occurred with a rate of 0.25 events per 100 subjects in clinical trials.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to the manufacturer via the stated contact in this leaflet

**4.9 Overdose**
Overdose can cause iron overload which may manifest itself as haemosiderosis. Overdose should be treated, as deemed necessary by the treating physician, with an iron chelating agent or according to standard medical practice.

# 5. Pharmacological properties

**5.1 Pharmacodynamic properties**

The polynuclear iron(III)-hydroxide cores are superficially surrounded by a number of non-covalently bound polymaltose molecules resulting in an overall complex molecular mass (Mw) of approximately 50 kD, which is so large that diffusion through the membrane of mucosa is about 40 times smaller than that of the hexaqua-iron(II) units. The complex is stable and does not release ionic iron under physiological conditions. The iron in the poly-nuclear cores is bound in a similar structure as in the case of physiologically occurring ferritin. Due to this similarity, only the iron (III) of the complex is absorbed by an active absorption process. By means of competitive ligand exchange, any iron binding protein in the gastro-intestinal fluid and on the surface of the epithelium, take up iron (III). The absorbed iron is stored mainly in the liver, where it is bound to ferritin. Later in the bone marrow, it is incorporated into haemoglobin.

Iron (III)-Hydroxide Polymaltose Complex has no pro-oxidative properties such as there are in iron II) salts. The susceptibility of lipoproteins such as Very Low Density Lipoprotein (VLDL) + Low Density Lipoprotein (LDL) to oxidation is reduced.

**5.2 Pharmacokinetic properties**

Studies using the twin-isotope technique (55Fe and 59Fe) show that absorption of iron measured as haemoglobin in erythrocytes is inversely proportional to the dose given (the higher the dose, the lower the absorption). There is a statistically negative correlation between the extent of iron deficiency and the amount of iron absorbed (the higher the iron deficiency, the better the absorption). The highest absorption of iron is in the duodenum and jejunum. Iron which is not absorbed is excreted via the faeces. Excretion via the exfoliation of the epithelial cells of the gastro-intestinal tract and the skin as well as perspiration, bile and urine only amount to approximately 1 mg of iron per day. For women, iron loss due to menstruation has also to be taken into account.

# 6. Pharmaceutical particulars

**6.1 List of excipients**
Dried Maize Starch

Colloidal silicon dioxide

Talcum Powder

**6.2 Incompatibilities**
Not applicable.

**6.3 Shelf life**
Shelf life of the product as packaged for sale

3 years.

**6.4 Special precautions for storage**
Store below 30°C in its original package.

**6.5 Nature and contents of container**

Capsule shells in PVC-Alufoil blisters packed in preprinted paper outer carton box

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

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

# 7. Marketing authorisation holder

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# 8. Date of revision of the text

**23/10/2019**