SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

ELERON SYRUP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Medicinal product contains Poly FZ syrup

Each 5ml of the syrup contains the following ingredients:

Iron (III) Hydroxide Polymaltose …50mg

Folic Acid……2.5mg

Vitamin B12 ……7.5mg

Zinc Sulphate……1.5mg

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL Form

200ml amber coloured glass bottle, sealed with P.P. cap in a carton along with measuring cup

and leaflet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Prevention & treatment of all kind of iron deficiencies particularly iron deficiency anaemia & for the prevention of folic acid, vitamin B group and zinc deficiency. The liquid formulation is especially for the prophylactic therapy of iron deficiency to cover the recommended daily dietary allowances for children adolescents.

4.2 Posology and method of administration

For oral use only.

Children: 2yrs -6yrs: 5ml 2-3 times daily

7yrs -14yrs: 10ml 2-3 times daily

Adult: 10ml 3 times daily

4.3 Contraindications

- Use in patients with a known hypersensitivity to any of the active ingredients.
- Use in patients with anaemia of undiagnosed aetiology.

4.4 Special warnings and precautions for use

This product should be used with caution in patients with haemochromatosis and haemolytic anaemia

4.5 Interaction with other medicinal products and other forms of interaction

Iron absorption from iron polymaltose complex was not reduced by aluminium hydroxide or tetracycline. Iron (III) hydroxide polymaltose complex can therefore be administered at the same time as tetracycline or other phenolic compounds, as well as aluminium hydroxide. Animal studies with tetracycline, aluminium hydroxide, acetylsalicylate, sulphasalazine, calcium carbonate, calcium acetate and calcium phosphate in combination with vitamin D3, bromazepam, magnesium aspartate, D-penicillamine, methyldopa, paracetamol and auranofin have not shown any interactions with iron polymaltose complex.

4.6 Pregnancy and lactation

Iron polymaltose complex have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus after the first trimester. Studies in animals have not shown any direct or indirect toxicity affecting pregnancy, embryo development or foetal development.

Human breast milk naturally contains iron, which is bound to lactoferrin. The amount of iron passing from iron polymaltose to the mother's milk is unknown. However, during pregnancy and lactation, this medicine should be used only if the potential benefit outweighs the risk.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Side effects include nausea, diarrhoea, constipation may occur rarely.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

Symptoms of overdosage with iron salts include nausea and vomiting, abdominal pain, vomiting of blood and circulatory collapse. In severe cases,

encephalopathy, acute hepatic necrosis and acute renal failure may develop after a latent period.

Treatment consists of gastric lavage followed by the introduction of 5 g desferrioxamine into the stomach. Serum iron levels should be monitored. In severe cases intravenous desferrioxamine should be administered together with supportive and symptomatic measures as required.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Iron preparations.

ATC Code: B03AB05

In iron (III)-hydroxide polymaltose complex, the polynuclear iron (III)-hydroxide core is superficially surrounded by a number of non-covalently bound polymaltose molecules resulting in an overall average molecular weight of approximately 50 kDa. The polynuclear core of IPC has a structure similar to that of the physiological iron storage protein, ferritin. IPC is a stable complex and does not release large amounts of iron under physiological conditions. Because of its size, the extent of diffusion of IPC through the membrane of the mucosa is about 40 times less than that of the hexaquo-iron (II) complex. Iron from IPC is taken up in the gut via an active mechanism. In contrast to iron (II) salts, IPC does not have pro oxidative properties.

5.2 Pharmacokinetic properties

Studies using the twin-isotope technique (55Fe and 59Fe) have shown 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 1mg of iron per day. For women, iron loss due to menstruation has also to be taken into account.

Folic acid is rapidly absorbed from the gastrointestinal tract, mainly from the duodenum and jejunum. Dietary folates are stated to have about half the bioavailability of crystalline folic acid.

Vitamin B12 substances bind to an intrinsic factor, a glycoprotein secreted by the gastric mucosa, and are then actively absorbed from the gastrointestinal tract. Absorption from the gastrointestinal tract can also occur by passive diffusion; little of the vitamin present in food is absorbed in this manner although the process becomes increasingly important with larger amounts such as those used therapeutically. Zinc is incompletely absorbed from the gastrointestinal tract, and absorption is reduced in the presence of some dietary constituents such as phytates. Bioavailability of dietary zinc varies widely between different sources, but is about 20 to 30%. Zinc is distributed throughout the body with the highest concentrations found in muscle, bone, skin, and prostatic fluids. It is primarily excreted in the faeces, and regulation of faecal losses is important in zinc homoeostasis. Small amounts are lost in urine and perspiration.

5.3 Preclinical safety data

No LD50 for iron polymaltose could be determined in animal studies with white mice and rats up to an orally administered dose of 2,000mg of iron per kilogram body weight. Effects on fertility:

Fertility studies of iron polymaltose in animals did not reveal any effects on fertility or early embryonic development.

No effects of iron polymaltose on development or growth of off spring were observed in a pre/post-natal toxicity study in rats, in which nursing dams were treated throughout the preweaning lactation period. Preliminary data from studies conducted in juvenile rats showed no

treatment-related adverse effect when immature rats were directly treated orally with iron polymaltose from shortly after 6. Pharmaceutical particulars

6.1 List of excipients

Disodium Edetate

Sodium Citrate

Xanthan Gum

Methyl paraben

Propyl paraben

Citric Acid Monohydrate

Sodium Hydroxide

Propylene Glycol

Sugar (Food Grade)

Saccharin Sodium

Sorbitol

Chocolate Flavour

Sucrose

Purified Water

6.2 Incompatibilities

None known

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 30 °C.

6.5 Nature and contents of container

A 200ml amber coloured glass bottle shield with a cork.

Pack sizes: 200ml amber coloured glass bottle containing 200ml of the syrup packed in asecondary packaging carton with a measuring cup placed on the bottle along with a leaflet.

6.6 Special precautions for disposal and other handling

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

7. Marketing Authorization Holder and Manufacturing Site Address

Salom Pharmaceuticals Limited

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P. O. Box 4901, Adum,

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8. Marketing Authorization Number

H2014/CTD1833/500

9. Date of First Authorization or renewal

19/12/2018 & 17th July,2025

10. Date of revision of the text

24th February, 2026