

20-03-2018

## ELEZO<sup>®</sup> Capsules / Syrup

(Polysaccharide Iron Complex)

### DESCRIPTION:

**ELEZO<sup>®</sup>** is a highly water soluble complex of iron and a low molecular weight polysaccharide

**Actions and uses:** **ELEZO<sup>®</sup>** is an easily assimilated source of iron for treatment of uncomplicated iron deficiency anemia. Because **ELEZO<sup>®</sup>** is a polysaccharide bound iron complex, it is relatively nontoxic and there are relatively few, if any, gastrointestinal side effects associated with iron therapy, thus permitting full therapeutic dosage (150 - 300mg elemental iron daily) in a single dose if desirable. There is no staining of teeth and no metallic aftertaste

### COMPOSITION:

**ELEZO<sup>®</sup>** 150mg Capsules  
Each capsule contains:  
Polysaccharide Iron Complex MS  
equivalent to Elemental Iron.....150mg

**ELEZO<sup>®</sup>** 100mg/5ml Syrup  
Each 5ml contains:  
Polysaccharide Iron Complex MS  
equivalent to Elemental Iron.....100mg

### ABSORPTION:

The polysaccharide iron complex (PIC) in **ELEZO<sup>®</sup>** is an ionized iron delivery system that allows the ionic iron to be delivered to the bloodstream, without coming into contact with the stomach or upper GI tract. **ELEZO<sup>®</sup>** is absorbed intact through the small intestine where it is then delivered to the bloodstream. There, the polysaccharide starch is broken away from the ionic iron by an enzymatic process. This process can occur because of the unique polarity of the PIC. Once free from the PIC, the ionized iron can be used by the body to make hemoglobin

### PHARMACOLOGY:

#### Mechanism of action

Iron is an essential component in the formation of hemoglobin. Iron deficiency generally develops slowly and is not clinically apparent until anemia is present as a severe stage of iron deficiency

**ELEZO<sup>®</sup>** PIC is derived by chemical complexation of elemental iron with polysaccharides formed by partial acid hydrolysis of starch under controlled conditions. It is unique because of its low molecular weight of approximately 600g/mol and its straight-chained molecular configuration

The chemical structure of PIC differs substantially from conventional oral iron products (ferrous sulfate, gluconate and fumarate). PIC is a non-ionic, low molecular weight complex composed of spheres which range in diameter from 3 to 10nm. The spheres are composed of iron atoms interspersed among tightly packed oxygen atoms. These spheres are surrounded by a polysaccharide coat. PIC contains no free iron ions and is capable of maintaining relatively high concentrations of iron in a soluble, nontoxic form at physiological pH

### INDICATION AND CLINICAL USE:

**ELEZO<sup>®</sup>** (polysaccharide iron complex) is indicated for:

- Prevention and treatment of all kinds of iron deficiencies particularly iron deficiency anemia in pregnant and lactating women, children, adolescents and adults

### DOSAGE AND ADMINISTRATION:

For capsule:

- Usual adult dose of **ELEZO<sup>®</sup>** 150mg is 1 to 2 capsules daily
- For patients who may have difficulty in swallowing capsules, the capsule can be opened and the powder can be diluted in liquid or sprinkled on food

For syrup:

| For Prevention of Iron Deficiency Anemia |                             | For Treatment of Iron Deficiency Anemia |   |
|--|-----------------------------|---|---|
| Children from 6 months to 23 months      | 2mg/kg/day                  | Infants & Children                      | 3-6mg/kg (maximum 200mg) of elemental iron daily in 2-3 divided doses |
| Children from 24 months to 59 months     | 2mg/kg/day up to 30mg daily |   |   |
| Children from 5 years to 11 years        | 30-60mg daily               | Adults & Elderly                        | 5ml once or twice a day (100-200mg of elemental iron daily)           |
| Older (11 years & above)                 | 60mg daily                  |   |   |

OR  
As directed by the physician

### CONTRAINDICATIONS:

**ELEZO<sup>®</sup>** (polysaccharide iron complex) is contraindicated in:

- Hemodilution
- Hemochromatosis
- Known hypersensitivity to any of the components of this product

### PRECAUTIONS:

*General:* The type of anemia and underlying cause or causes should be determined before starting therapy with polysaccharide iron complex. Since the anemia may be a result of a systemic disturbance e.g. recurrent blood loss, the underlying cause(s) should be corrected. Patients should not exceed the recommended dosage unless directed by physician. Patients should be informed that iron therapy can cause black or dark stools

### UNDESIRABLE EFFECTS:

Some people may experience gastrointestinal side effects

### INTERACTIONS:

Until now, interactions have not been observed. Interactions may occur with these drugs especially chloramphenicol, penicillamine, methylopa, levodopa, cimetidine, quinolone antibiotics (e.g. ciprofloxacin, norfloxacin). Avoid taking iron concomitantly with antacids or tetracycline antibiotics. Wait at least 2 hrs. between taking iron and antacid or tetracycline

### STABILITY:

See expiry on the pack

### PRESENTATION:

**ELEZO<sup>®</sup>** 150mg capsules in a pack of 30's  
**ELEZO<sup>®</sup>** 100mg/5ml syrup in a pack of 120ml

### INSTRUCTIONS:

Keep out of reach of children  
Avoid exposure to heat, light, humidity and freezing  
Store between 15 to 30°C  
Improper storage may deteriorate the medicine

Medicine should not be used if container is leaking or it contains undissolved particle(s)

Manufactured by:  
SAMI Pharmaceuticals (Pvt.) Ltd.  
F-95, S.I.T.E., Karachi-Pakistan  
www.samipharmapack.com

ایلی زو<sup>®</sup> کیپسول / سیرپ  
(پولی سیکریٹو آئرن کمپلیکس)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں

بچوں کی پختی سے دور رکھیں

دوا کو دھوپ، گرمی، نمی اور نمند ہونے سے محفوظ رکھیں ۱۵ سے ۳۰ ڈگری سینٹی گریڈ

کے درمیان میں رکھیں درندہ خراب ہو جائیگی

دوا کے ایک ہونے یا اس میں کوئی غیر حل پذیر شے نظر آنے کی صورت میں ہرگز استعمال نہ کریں

R.N-03/HA/03/18-S/5

150 mm

210 mm