SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Niferex Elixir

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of elixir contains 217.4mg of Polysaccharide-iron complex

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution.

Dark brown liquid with a slightly sweet taste.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

For the prophylaxis and treatment of uncomplicated iron deficiency anaemia.

4.2 Posology and method of administration

Posology

Niferex Elixir 30 ml paediatric dropper bottle should not be used in infants older than 6 months of age. For children older than 6 months, the 190ml Niferex Elixir should be used for dosing.

Each 5 ml of Niferex Elixir contains 217.4 mg of polysaccharide-iron complex equivalent to 100mg of elemental iron.

Adults:

Prophylactic Dose	2.5 ml daily (50mg elemental iron daily)
Therapeutic Dose	5 ml once or twice daily (100-200mg elemental iron daily)

Paediatric population:

Prophylaxis of iron deficiency

Recommended daily dose of elemental iron for prophylaxis of iron deficiency (see also Section 4.4):

Group	**Dose of elemental iron Given in 2-3 divided dose**
Low birth weight babies who are solely breast fed	5 mg/day Higher doses up to 2mg/kg/day might be needed to cover the needs of growing exclusively breastfed infants. Supplementation is started 4-6 weeks after birth and continued until mixed feeding is established
Children from 6 to 23 months	2mg/kg/day
Children from 24 to 59 months	2mg/kg/day up to 30mg/day
Children from 5yrs to 11 yrs	30-60mg/day
Older children	60mg/day

Treatment of Iron deficiency anaemia

Treatment of iron deficiency anaemia in all paediatric age groups is 3-6mg/kg/day (max.200mg) of elemental iron in 2-3 divided doses.

Elderly Patients:
The normal adult dose is appropriate.

Pregnancy (during second and third trimester):
5ml daily (100mg elemental iron daily).

Method of administration
For oral use.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
- Known iron overload.
- Haemosiderosis and haemochromatosis.
- Active peptic ulcer.
- Repeated blood transfusion.
- Regional enteritis and ulcerative colitis.
- Haemolytic anaemias.

4.4 Special warnings and precautions for use

Patients post-gastrectomy have poor absorption of iron. Caution is advised when prescribing iron preparations to individuals with history of peptic ulcer.

Duration of treatment should generally not exceed 3 months after correction of anaemia.

Co-existing deficiency of vitamin B_{12} or folic acid should be ruled out since combined deficiencies produce microcytic blood film.

Iron deficiency in a male patient warrants careful investigation to determine its cause which forms the basis of primary treatment.

Patients suffering from iron overload are particularly susceptible to infection. Treatment of iron overload should be with caution.

The label will state:

Important warning: Contains Iron. Keep out of the sight and reach of children, as overdose may be fatal.

This will appear on the front of the pack within a rectangle in which there is no other information.

4.5 Interaction with other medicinal products and other forms of interaction

Iron and tetracyclines interfere with absorption of each other.

Iron and zinc interfere with the absorption of each other.

Absorption of iron is impaired by magnesium trisilicate, trientine, antacids, neomycin, cholestyramine, tea, eggs or milk.

Absorption of penicillamine, levodopa, bisphosphonates, ciprofloxacin, norfioxacin and ofloxacin is reduced by iron.

Chloramphenicol delays plasma clearance of iron and incorporation of iron into red blood cells by interfering with erytbropoxesxs.

4.6 Fertility, pregnancy and lactation

Pregnancy
Administration of drugs during the first trimester of pregnancy requires careful assessment of potential risks versus benefits to be gained and should not be administered unless clearly indicated. For the remainder of the pregnancy, iron therapy may be indicated but only on advice of a physician.

Breast-feeding

Iron is excreted in breast milk but not in clinically significant concentrations (about 0.5mg/day).

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Anorexia, nausea, vomiting, gastro-intestinal discomfort, constipation, diarrhoea, dark stools and allergic reactions. These side-effects may be minimised by taking the elixir after food.

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 via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

4.9 Overdose

Iron overdose is an acute emergency requiring urgent medical attention. An acute intake of 75mg/kg of elemental iron is considered extremely dangerous in young children.

Symptoms: Initial symptoms of iron overdose include nausea, vomiting, diarrhoea, abdominal pain, haematemesis, rectal bleeding, lethargy and circulatory collapse. Hyperglycaemia and metabolic acidosis may also occur. However, if overdose is suspected, treatment should be implemented immediately. In severe cases, after a latent phase, relapse may occur after 24-48 hours, manifested by hypotension, coma, hypothermia, hepatocellular necrosis, renal failure, pulmonary oedema, diffuse vascular congestion, coagulopathy and/or convulsions. In many cases, full recovery may be complicated by long-term effects such as hepatic necrosis, toxic encephalitis, CNS damage and pyloric stenosis.

Treatment

The following steps are recommended to minimise or prevent further absorption of the medication:

Paediatric population:

1. Administer an emetic such as syrup of ipecac.

2. Emesis should be followed by gastric lavage with desferrioxamine solution (2g/l). This should then be followed by the installation of desferrioxamine 5mg in 50-100ml water, to be retained in the stomach. Inducing diarrhoea in children may be dangerous and

should not be undertaken in young children. Keep the patient under constant surveillance to detect possible aspiration of vomitus, maintain suction apparatus and standby emergency oxygen in case of need.

3. Severe poisoning: In the presence of shock and/or coma with high serum iron levels (serum iron> 90 micromolll) immediate supportive measures plus IV. infusion of desferrioxamine should be instituted. Desferrioxamine 15mg/kg body weight should be administered every hour by slow I.V. infusion to a maximum 80mg/kg/24 hours

   Warning: Hypotension may occur if the infusion rate is too rapid.

4. Less severe poisoning: I.M. desferrioxamine ig 4-6 hourly is recommended.

5. Serum iron levels should be monitored throughout.

Adults:

1. Administer an emetic.

2. Gastric lavage may be necessary to remove drug already released into the stomach. This should be undertaken using a desferrioxamine solution (2g/l).

   Desferrioxamine 5g in 50-100ml water should be introduced into the stomach following gastric emptying. Keep the patient under constant surveillance to detect possible aspiration of vomitus, maintain suction apparatus and standby emergency oxygen in case of need.

3. A drink of mannitol or sorbitol should be given induce small bowel emptying.

4. Severe poisoning: In the presence of shock and/or coma with high serum iron levels (> 142 micromol/l) immediate supportive measures plus I.V. infusion of desferrioxamine should be instituted. The recommended dose of desferrioxamine is 5mg/kg/h by slow I.V. infusion up to a maximum of 80mg/kg/24 hours.

   Warning: Hypotension may occur if the infusion rate is too rapid.

5. Less severe poisoning: I.M. desferrioxamine 50mg/kg up to a maximum dose of 4g should be given.

6. Serum iron levels should be monitored throughout.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Iron preparations
ATC code: B03A

Niferex polysaccharide-iron complex is a source of iron, which is an essential constituent of the body being necessary for haemoglobin formation and for the oxidative processes of living tissues.

5.2 Pharmacokinetic properties

Absorption
Niferex is a highly water-soluble polysaccharide-iron complex which is stable in the range pH 4.5 to 11.0 and which disassociates only after leaving the stomach.

The iron is released for absorption from the intestinal tract, over a period of one hour, with subsequent significant and effective plasma levels.

Biotransformation
Pharmacokinetic study of oral polysaccharide-iron complex in rats shows absorption rate constant (Ka) of 2.33 hours, 19 fold greater than elimination rate constant as obtained from the terminal exponential fraction (Kel-0. 12 hours'). A lag time before absorption of 12 minutes was observed.

tmax = 60 minutes
Cinax = 200 micrograms Fe/100 ml
t½ = 5.8 hours

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethyl alcohol (96%)
Sorbitol solution 70% (non-crystallising)
Caramel
Hydrochloric acid
Purified water

6.2 Incompatibilities

No known incompatibilities other than those stated in Section 4.5. above.

6.3 Shelf life

The shelf life of Niferex Elixir, as packaged for sale, is 3 years.

There are no recommendations for dilution or reconstitution of the product.

There is no information on the shelf life of the product after first opening the container.

6.4 Special precautions for storage

Store below 25ºC.

6.5 Nature and contents of container

(a) 30 ml paediatric dropper bottle
Plastic (low density polyethylene) bottle with a plastic dropper applicator. The screw cap is composed of high density polyethylene.

(b) 190ml
Glass bottle with childproof screw cap closure.

(c) 240ml bottle
Glass bottle with a plastic screw cap closure.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements for disposal
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Tillomed Laboratories Limited
220 Butterfield
Great Marlings
Luton
LU2 8DL
UK

8. MARKETING AUTHORISATION NUMBER(S)

PL 11311/0023

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08/02/1995
Date of latest renewal: 01/04/2009

10 DATE OF REVISION OF THE TEXT

04/02/2020