SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

ARBICI (Ferrous Sulfate Oral Solution USP 40 mg Fe/5mL)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Ferrous Sulfate USP	200 mg
equivalent to Elemental Iron	40 mg
Colour: Ponceau 4R supra, Chocolate Brown	
Flavoured syrup base	q. s.

3 PHARMACEUTICAL FORM

Oral Solution
A reddish brown coloured clear liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For prevention and treatment of iron deficiency anaemias.

4.2 Posology and method of administration

Method of administration
Oral

Posology

Prophylactic:

A daily dose of 5 mg of elemental iron as prophylactic iron supplementation for babies of low birth weight who are solely breast-fed is recommended. Higher doses up to 2mg/kg of elemental iron per 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.

Older infants and children to 6 years: 0.5 – 1.2 ml per day (12.5 – 30 mg elementaliron).
Older children: 2.4 ml per day (60 mg elemental iron).
Adults and Elderly: 2.4 – 4.8 ml per day (60 – 120 mg of elemental iron)

Therapeutic:

Paediatric: 0.12ml to 0.24ml (3mg – 6mg elemental iron) per kg body weight, up to a maximum of 8ml (200mg elemental iron) given daily in two or three divided doses.

Adults: 4.0 ml once or twice per day (100 – 200 mg elemental iron)

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed insection 6.1.

Contraindicated for use in patients with the following conditions: Haemosiderosis and haemocromatosis, 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 1-2 months after end ofpregnancy.
- Coexisting deficiency of dietary vitamin B12 should be ruled out since combined deficiency produces microcytic blood film.
- Care should be taken in patients with intestinal strictures and diverticulae.
- Caution is required in the elderly where there is an increased risk of faecalimpaction.
- The label will state “Important warning: Contains iron. Keep out of the reach and sight 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.
- Metabisulfite can cause allergic reactions (such as skin rash and fluid retention) and bronchospasm (asthma-like difficulty in breathing) in susceptible individuals.
- This medicine contains 2075mg of sorbitol in each 4.8ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

- This medicine contains 623 mg propylene glycol in each 4.8ml. If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propyleneglycol or alcohol.

4.5. Interactions with other medicinal products and other forms ofinteraction

- Iron and tetracyclines interfere with absorption of each other.
- Absorption of iron is impaired by penicillamine, antacids, cholestyramine, tea, eggs and milk.
- Chloramphenicol delays plasma clearance of iron, incorporation of iron into red blood cells by interfering with erythropoiesis.

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 ARBICI should not be administered unless clearly indicated.

4.7 Effects on ability to drive and use machines

ARBICI Drops has no or negligible influence on the ability to drive and usemachines.

4.8 Undesirable effects

Anorexia, nausea, vomiting, gastrointestinal discomfort, reversible dental staining, constipation, diarrhoea, dark stools and allergic reactions. The product contains metabisulfite as a preservative which can precipitate allergic reactions and bronchospasm in susceptible individuals.

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 reactionsvia the Yellow Card Scheme:
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9. Overdose

Iron overdosage is an acute emergency requiring urgent medical attention. An acute intake of 75mg/Kg of elemental iron is considered extremely dangerous in young children. Serum iron levels should be monitored.
Symptoms and signs include abdominal pain, diarrhoea and vomiting (haematemesis is a possibility) within 1 - 2 hours, followed by cardiovascular collapse and coma in some patients. Recovery follows this phase and in some patients this continues; in others, deterioration occurs in about 15 hours characterised by diffuse vascular congestion, pulmonary oedema, convulsion, hypothermia, renal failure, shock, metabolic acidosis, coagulopathy and/or hypoglycaemia. Treatment consists of supportive and symptomatic measures. Vomiting should be induced if the patient presents early and gastric lavage should be considered using a solution of desferrioxamine. Parenteral injection of 2g desferrioxamine should be given IV or IM and 5g of desferrioxamine in 50 - 100ml of fluid may also be left in

the stomach.
Recovery may be complicated by long term effects such as hepatic necrosis, toxic encephalitis and CNS damage, and pyloric stenosis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Iron Preparations, Iron bivalent, oral preparations, ferroussulfate.

ATC Code: B03AA07

5.2. Pharmacokinetic properties

The active is in solution and readily absorbed as the ferrous salt.

5.3. Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sr. No.	Raw Material	Pharmacopoeia
1.	Sucrose	BP
2.	Methyl Hydroxybenzoate	BP
3.	Propyl Hydroxybenzoate	BP
4.	Propylene Glycol	BP
5.	Glycerin	BP
6.	Sorbitol 70 %	BP
7.	Essence Peppermint	IHS
8.	Sodium Benzoate	BP
9.	Citric Acid	BP
10.	Sodium Metabisulfite	BP
11.	Colour Ponceau 4R supra	IHS
12.	Colour chocolate Brown	IHS
13.	Purified Water	BP

6.2 Incompatibilities

None

6.3. Shelf life

36 months.

6.4 Special precautions for storage

Store below 30ºC in dark place. Do not freeze.

6.5 Nature and contents of container

60 ml filled in Amber Coloured PET Bottle packed in carton.

6.6 Special precautions for disposal

No special requirements

7. Marketing authorisation holder

Kilitch Drugs (India) Limited
37, Ujagar Industrial Estate,
W.T Patil Marg, Deonar,
Mumbai 400 088,Maharashtra, India.
Website- www.kilitch.com

8. Marketing authorisation number(s) issued by Ethiopian FDA and date of MA authorization

07312/07706/VAR/2021

9. Date of first authorisation/renewal of the authorisation

13-04-2022

10. Date of revision of the text

08/07/2023