Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product

AGIFER-X 50MG/ 5ML SYRUP

2. Quality and quantitative composition

Each 5 mL contains Iron (III) hydroxide polymaltose complex Eq. to elemental iron 50mg

3. Pharmaceutical form

Syrup.

Dark brown coloured pleasantly flavored liquid.

4. Clinical particulars

4.1 Therapeutic indications

Haematinic containing iron (Ill) hydroxide polymaltose complex for correction of anaemia and also for prophylactic use. Indicated in all cases of iron deficiency and iron deficiency anaemia as in: Pregnancy, Lactation, Childhood, Post-surgical conditions and others.

4.2 Posology and method of administration Dosage

Adults: 5 mL, 2-3 times daily.

Children: 5 mL, 1-2 times daily.

Infants: Begin with 2.5 mL once or twice daily. Depending on the clinical improvement of the patient, increase the dose to 5 mL once or twice daily.

Agifer-X Syrup may be mixed with fruit or vegetable juices or other liquids if desired. Best results obtained by adequate dosage and regular administration. It is recommended that the therapy in conformity to the degree of iron deficiency should be continued for at least 1-2 months. Or as directed by the Physician.

Method of administration: For oral use. Shake well before use.

4.3 Contraindications

Iron overload (E.g. hemochromatosis, hemosiderosis) or disturbances in iron utilization (E.g. Lead anemia, sideroachrestic anemia, thalassemia) and anemias not caused by iron deficiency (E.g. hemolytic anemia).

4.4 Special warnings and precautions for use

A dark coloration of the stool, which occurs with all therapy involving iron preparations, is without significance.

4.5 Interaction with other medicinal products and other forms of interaction

No interactions are evident either with food or medications, contrary to what happens with ferrous salts.

4.6 Pregnancy and lactation

This product should only be used in pregnancy after the first thirteen weeks.

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

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 AGIFER-X syrup is unlikely to cause undesirable effects to the nursed child. During pregnancy and lactation AGIFER-X syrup should be used only after consulting a physician.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

• Very Common – Discolored faeces
• Common – Diarrhoea, Nausea, Dyspepsia
• Uncommon – Vomiting, Constipation, abdominal pain, Tooth discoloration, Rash, Pruritus, Headache.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization 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 Pharmacy and Poisons Board-Pharmacovigilance Electronic Reporting System (PvERS); https://pv.pharmacyboardkenya.org .

4.9 Overdose

Signs and symptoms of severe iron poisoning consist largely of abdominal pain, diarrhoea or vomiting brown or bloody stomach contents of particular concern are pallor or cyanosis, lassitude, drowsiness, hyperventilation due to acidosis, and cardiovascular collapse.

Above side-effects are not reported with iron (III) hydroxide polymaltose complex, as it responds to the same regulatory mechanism that dictates absorption from the intestinal lumen to balance requirements of the individual. Absorption of iron (III) hydroxide polymaltose complex is by active transport instead of passive diffusion.

If any of the above symptoms appear due to very high dose then, deferoxamine should be administered.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-anaemic preparations, iron preparations, Iron trivalent, oral preparations

ATC Code: B03AB

Iron (III) hydroxide polymaltose complex is essentially non-ionic form of iron. Iron (III) hydroxide polymaltose complex does not cause unwanted side effects usually obtained with ionised iron salt preparations such as gastrointestinal irritation, teeth staining, metallic taste, reduced iron absorbability due to interactions with food components and medicaments containing phenolic groups (e.g. Tetracyclines) taken simultaneously. Apart from their excellent tolerance, iron (III) hydroxide polymaltose complex guarantees a high safety margin. The acute oral toxicity of iron

(III) hydroxide polymaltose complex is so low that iron poisoning after accidental iron overdose can be excluded.

5.2 Pharmacokinetic properties

The bioavailability of iron (III) hydroxide polymaltose is equivalent to ferrous salt. This results in a fast utilisation of the iron administered in haemoglobin and myoglobin (tissue iron)-synthesis and replenishment of iron depots. Symptoms seen in iron deficiency states are improved.

5.3 Preclinical Safety data

None available

6. Pharmaceutical particulars

6.1 List of excipients

Methyl Hydroxybenzoate BP
Propyl Hydroxybenzoate BP
Liquid Sorbitol Solution 70% (Non-Crystallising) BP
Sucrose BP
Creamy Milk T.P. Flavour (010264) IH
Sodium Hydroxide pellets BP
Purified Water BP

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

150mL syrup filled in an amber colour PET bottle. 1 such bottle is packed in a carton along with pack insert.

6.6 Special precautions for disposal

None

7. Marketing Authorization Holder

AGIO PHARMACEUTICALS LTD,
A – 38, Nandjyot Industrial Estate,
Safed Pool, Kurla – Andheri Road,
Mumbai – 400072, India.

8. Marketing authorization number(s)

H2026/CTD8404/16817

9. Date of first registration/ renewal of the registration

2026 June 05

10. Date of revision of the text

2026 June 05