Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product

AGIFER-X CAPSULE

2. Quality and quantitative composition

Each hard-gelatin capsule contains Iron (III) hydroxide polymaltose complex Eq. to Elemental iron 100 mg and Folic Acid BP 550 mcg

Excipients with potential clinical effect:

Each hard-gelatin capsule contains Lactose monohydrate

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Hard-Gelatin Capsule.

Hard gelatin capsules of size '2' having maroon cap and maroon body, both printed with "Agifer X" containing dark brown colour powder.

4. Clinical particulars

4.1 Therapeutic indications

Haematinic containing Iron (Ill) hydroxide polymaltose complex for correction of anaemia and also for prophylactic use.

- For the treatment of Iron deficiency anemia during
- Pregnancy
- Lactation
- Anameia due to post-partum haemorrhage
- For the prevention of Iron deficiency anemia

4.2 Posology and method of administration

Dosage: As directed by the Physician

Method of administration: For oral use.

4.3 Contraindications

- Iron overload
- Thalassemia
- Non-iron deficiency anaemias (like haemolytic anaemia)

4.4 Special warnings and precautions for use

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

Precautions for use: No special precaution is required.

Iron polymaltose complex can be safely used in pregnancy and lactation.

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

Negative influence on the foetus or the woman during pregnancy or breast-feeding is unlikely according to the available data. However, during pregnancy and lactation AGIFER-X capsule should be used only after consulting a physician.

4.7 Effects on ability to drive and use machines

No evidence found.

4.8 Undesirable effects

Gastrointestinal irritation with flatulence, epigastric malaise nausea, constipation or diarrhoea may occasionally occur. A dark colour of faeces can be seen without having clinical significance.

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

In overdose cases, no iron overload or toxicity has been reported.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-anaemic preparations, iron preparations, Iron trivalent, Iron in combination with folic acid
ATC Code: B03AD04

Agifer-X capsules contain Iron (III) hydroxide polymaltose complex which is a non-ionic iron source. Due to rapid absorption, it's high rate of iron utilization, effective haemoglobin production by iron polymaltose complex and excellent gastrointestinal tolerance, Agifer-X capsules becomes an ideal preparation for iron deficiency anaemias. Unlike ferrous salts where disturbances due to gastrointestinal intolerance is very common, iron polymaltose complex in Agifer-X capsules is well toleraled by gastrointestinal tract and hence increases patient compliance. This bioavailability of iron polymaltose is equivalent to ferrous salt. This results in a last utilisation of the iron administered in haemoglobin synthesis and replenishment of iron depots.

Folic acid is a member of vitamin B group, which is essential for DNA synthesis. Folic acid deficiency is an important cause of anaemia. The requirements of folic acid are increased during pregnancy. Folic acid is very important in the prevention of many chronic diseases and neural tube defects in new born.

5.2 Pharmacokinetic properties

Iron polymaltose complex is absorbed at a slower rate than inorganic salts or other iron complexes like iron ascorbate i.e. they have a different pharmacokinetic behaviour, especially in non-anaemic individuals. This slower absorption increases the safety profile of the iron polymaltose complex. After 3 months of treatment, both iron polymaltose complex and ferrous salts yield equal results.

Agifer-X capsule is used to correct Iron deficiency anaemia and nutritional anaemia that occurs especially during pregnancy and lactation. Being non-ionic Iron, iron polymaltose complex in Agifer-X capsules does not release free Iron radicals unlike other Iron salts. The LD 50 of iron polymaltose complex is very high (greater than 2000 mg/kg

bw). This may prevent toxicity due to inadvertent overdosing. No food or medicaments are known to Interact or interfere in the Iron absorption from iron polymaltose complex. Hence Agifer-X capsules can be taken either before or after meals.

5.3 Preclinical Safety data

None available

6. Pharmaceutical particulars

6.1 List of excipients

Lactose Monohydrate (DCL-11) BP
Sodium Lauryl Sulphate BP
Purified Talc BP
Magnesium Stearate BP
E.H.G. Capsule Shell Size '2' Maroon Cap and Maroon Body IH

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 30°C. Protect from moisture.

6.5 Nature and contents of container

2 composite blister packs of 2 x 10 capsules 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/CTD8405/16769

9. Date of first registration/ renewal of the registration

2026 June 05

10. Date of revision of the text

2026 June 05