

PATIENT INFORMATION LEAFLET

1. Name of Product

SOLFER LITE (Iron (III) Hydroxide Polymaltose complex and Folic acid Capsules)

2. Description of Product

A Scarlet/Scarlet hard gelatin capsules Size “2” containing brown coloured powder.

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet,
- please tell your doctor or pharmacist.

In this leaflet:

1. What **SOLFER LITE** are and what they are used for
2. Before you take **SOLFER LITE**
3. How to take **SOLFER LITE**
4. Possible side effects
5. How to store **SOLFER LITE**
6. Further information

1. WHAT SOLFER LITE (Iron (III) Hydroxide Polymaltose complex and Folic acid Capsules) IS AND WHAT IT IS USED FOR

It is used to treat:

- Anaemia
- Coeliac disease
- Folate-deficient megaloblastic anaemia
- For prophylaxis in chronic haemolytic states or in renal dialysis
- For prophylaxis in pregnancy
- Haemolytic anaemia
- Megaloblastic anaemia
- Myelofibrosis
- To prevent 1st occurrence of neural tube defect, To prevent recurrence of neural tube defect
- Vitamin deficiency
- Iron-deficiency anemia.

SOLFER LITE

(Iron (III) Hydroxide Polymaltose Complex and Folic Acid Capsules)



2. BEFORE YOU TAKE SOLFER LITE (Iron (III) Hydroxide Polymaltose complex and Folic acid Capsules)

Tell your doctor if you:

- are allergic (hypersensitive) to Iron (III) Hydroxide Polymaltose Complex and Folic Acid or any of the other ingredients of this medicine.
- have cancer (unless you have anaemia due to a deficiency of folic acid)
- have any symptoms of hypersensitivity that may develop during and following Iron (III) Hydroxide Polymaltose Complex administration, such as rash, itching, dizziness, light headedness, swelling, and breathing problems

Take special care with SOLFER LITE (Iron (III) Hydroxide Polymaltose complex and Folic acid Capsules) and tell your doctor:

- if you are receiving a coronary stent (a tube that is inserted in the artery that leads to the heart, in order to stop blockages)
- if you have a tumour
- if you suffer from pernicious anaemia (a disorder preventing the absorption of vitamin B12) or could be
- suffering from a lack of vitamin B12
- if you are undergoing haemodialysis due to kidney failure

Taking other medicines

Before taking SOLFER LITE (Iron (III) Hydroxide Polymaltose complex and Folic acid Capsules), tell your doctor if you are taking or have taken recently any of the following medicines or are taking any non-prescribed medicines:

- Phenytoin, phenobarbital and Primadone (used to control epileptic fits)
- Fluorouracil, a drug used to treat certain tumours
- Antibiotics. Some antibiotics (trimethoprim and sulphonamides, sometimes combined as co-trimoxazole)
- reduce the effect of folic acid. All antibiotics can interfere with folic acid blood test results. Chloramphenicol may interfere with folate metabolism
- some indigestion remedies (edible clay and antacids containing aluminium or magnesium). Allow at least a two hour gap between taking **SOLFER LITE (Iron (III) Hydroxide Polymaltose Complex and Folic Acid Drop)** and indigestion remedies
- preparations containing zinc such as vitamins or food supplements (this may be important in pregnancy)
- sulfasalazine, used to treat the inflammatory bowel
- conditions ulcerative colitis and Crohn's disease
- cholestyramine, used to reduce cholesterol levels in the blood.
- methotrexate, used to treat Crohn's disease, rheumatoid
- arthritis or cancer.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

SOLFER LITE

(Iron (III) Hydroxide Polymaltose Complex and Folic Acid Capsules)



This medicine can be taken in pregnancy to treat Haemolytic anaemia, Megaloblastic anaemia, Myelofibrosis, To prevent 1st occurrence of neural tube defect, To prevent recurrence of neural tube defect, Vitamin deficiency.

If you are breast-feeding please speak with your doctor before taking this medicine.

Driving and using machines

There are no known effects of this preparation on the ability to drive or use machines.

3. HOW TO TAKE

Always take **SOLFER LITE** (Iron (III) Hydroxide Polymaltose complex and Folic acid Capsules) exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

As directed by physician.

For oral administration only.

Dose is based on patient's condition.

Do not stop taking this medicine unless your doctor tells you to stop.

If you take more than you should

If you take (or anybody else, including a child), takes more **SOLFER LITE** (Iron (III) Hydroxide Polymaltose complex and Folic acid Capsules) than you should, neither intoxication nor iron overload have been reported up to-date.

If you are at all concerned contact your doctor. Always take the bottle and leaflet with you.

If you forget to take the tablets

If you forget to take a dose, take it as soon as you remember, unless it is nearly time for your next dose. Then go on as before. Never double up on the next dose to make up for the one missed.

If you stop taking SOLFER LITE (Iron (III) Hydroxide Polymaltose complex and Folic acid Capsules) If you stop taking **SOLFER LITE** (Iron (III) Hydroxide Polymaltose complex and Folic acid Capsules) suddenly you may experience unpleasant side effects including Skin rash, itching, redness and difficulty in breathing. Withdrawal should be gradual.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, **SOLFER LITE** (Iron (III) Hydroxide Polymaltose complex and Folic acid Capsules) can have side effects, although not everybody gets them.

Stop treatment and contact a doctor at once if you have the following symptoms of an:

Skin rash, itching, redness and difficulty in breathing

SOLFER LITE

(Iron (III) Hydroxide Polymaltose Complex and Folic Acid Capsules)



5. HOW TO STORE

Keep out of the reach of children.

Store below 30⁰ C in a dry and dark place.

Protect from Light. Do not freeze.

6. FURTHER INFORMATION

What SOLFER LITE contain Excipients used in the formulation of **SOLFER LITE** (Iron (III) Hydroxide Polymaltose complex and Folic acid Capsules) Lactose BP, Colloidal Anhydrous Silica BP, Hard Gelatin Capsule shell Size '2' Scarlet/Scarlet (Colour code Index: #FF2400) IHS

Excipient with known effect: Lactose

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucosegalactose malabsorption should not take this medicine.

What SOLFER LITE looks like and contents of the pack

SOLFER LITE A Scarlet/ Scarlet hard gelatin capsules Size "2" containing brown coloured powder.

10 Capsule in Plain & Printed Polylaminated Aluminum Strip & 3 such Strips in a carton
= 3 x 10's = 30 Capsules

7. Name/logo of manufacturer/importer/Marketing Authorisation Holder

Name and Address of Manufacturer

Aurochem Pharmaceuticals (India) Pvt. Ltd.

Plot No.:58, Palghar Taluka,

Ind Co.-op. Estate Ltd. Boisar road,

Tal-Palghar,Thane – 401 404,

Tel No. : 0252-5252332, 0252-554720

Maharashtra State, INDIA.

Name and Address of Marketing Authorisation Holder

Aurochem Pharmaceuticals (India) Pvt. Ltd.

334, Gundecha Industrial Complex, 3rd Floor, Akurli Road.

Kandivali (E), Mumbai - 400101,

India.

Tel: +(91)-(22)- 42509191

Fax: +(91)-(22)- 42509150

E-mail: info@aurochempharma.com

website: www.aurochem.global

8 Date of Revision of PIL
