

SAFERON CHEWABLE TABLET

Iron (III) Hydroxide Polymaltose Complex/Folic acid (100mg/500mcg)

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What Saferon Chewable Tablets is used for

- Saferon Chewable Tablets is used for treatment of iron deficiency.

How Saferon Chewable Tablets works

- Iron (III) hydroxide polymaltose and folic acid involved in the formation of red blood cells.

Before you use Saferon Chewable Tablets

- When you must not use it

Do not use Saferon chewable tablet if:

- you are allergic (hypersensitive) to aspartame or to any of the other ingredients in this medicine.
- you are phenylketouric as this product contains aspartame

- Before you start to use it

- Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine. Saferon Chewable Tablets should not be taken in the first trimester of pregnancy and during breastfeeding.

- Taking other medicines

- Tell your doctor if you are taking any other medicines, including any that you buy

without a prescription from a pharmacy, supermarket or health food shop.

How to use Saferon

Chewable Tablets

- How much to use

- Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help. Using this medicine by chewing or swallowing whole. :

- Adult: 1 to 3 tablets daily

- When to use it

- Take Saferon chewable tablet in divided doses or can be taken at one time or as directed by your doctor or pharmacist.
- It should be taken during or immediately after a meal.

- How long to use it

- Use Saferon Chewable Tablets for 3 to 5 months or as the duration that the doctor recommends.

- If you forget to use it

- Consult your doctor or pharmacist on what you should do if you forget to use it.

- Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

- Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have use too much of this

medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

- Use your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are using Saferon Chewable Tablets.

- Things you must not do

- Do not stop using the medicine unless advised by your doctor.
- Do not use any new medicines without consulting your doctor or pharmacist.
- Do not give Saferon Chewable Tablets to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

- Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

- Rarely nausea, vomiting, diarrhea & constipation occurred.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

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Storage and Disposal of Saferon Chewable Tablets

- Storage

Store below 25°C. Protect from moisture & light

Keep medicine out of reach of children.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Satpur, Nasik - 422 007,
Maharashtra State, India.

Product Registration Holder

Glenmark Pharmaceuticals
(Malaysia) Sdn. Bhd.(660397-W)
D-31-02, Menara Suezcap 1,
No. 2, Jalan Kerinchi,
59200 Kuala Lumpur,
Malaysia

Date of Revision

- 15/08/2022

Serial Number

NPRA(R4/1)040822/00049

Product Description

- What it looks like

Brown coloured speckled, round biconvex, uncoated tablets with chocolate flavour and sweet taste.

- Ingredients

- Active ingredient(s)

Each chewable tablet contains Iron (III)-Hydroxide polymaltose complex equivalent to Elemental Iron 100mg and Folic acid 500mcg

- Inactive ingredients

Lactose, Colloidal Silicon Dioxide, Ethyl Cellulose 7cps, Sucrose, Mannitol, Dextrose Anhydrous, Cocoa Powder, Aspartame, Methyl Parahydroxybenzoate, Propyl Hydroxybenzoate, Sodium Starch Glycolate, Croscarmellose Sodium, Isopropyl alcohol, Purified talc, Vanilex Special-DG35301, Methylene chloride, Trusil Chocolate Special, Purified Water, Magnesium Stearate and Povidone.

- MAL number:

MAL06030848X

Manufacturer

Glenmark Pharmaceuticals Ltd,
Plot No. E-37, 39, D-Road MIDC,

SAFERON CHEWABLE TABLET

Iron (III) Hydroxide Polymaltose Complex/Folic acid (100mg/500mcg)

Apakah yang ada pada risalah ini

1. Apakah kegunaan Saferon Chewable Tablets
2. Bagaimana Saferon Chewable Tablets berfungsi
3. Sebelum menggunakan Saferon Chewable Tablets
4. Cara menggunakan Saferon Chewable Tablets
5. Semasa menggunakan Saferon Chewable Tablets
6. Kesan-kesan sampingan
7. Cara penyimpanan dan pelupusan Saferon Chewable Tablets
8. Maklumat lanjut
9. Pengilang dan Pemegang Pendaftaran Produk
10. Tarikh kemaskini RiMUP

Apakah kegunaan Saferon Chewable Tablets

- Saferon Chewable Tablets digunakan untuk rawatan kekurangan zat besi.

Bagaimana Saferon Chewable Tablets berfungsi

- *Iron (III) hydroxide polymaltose* dan *folic acid* terlibat dalam pembentukan sel darah merah.

Sebelum menggunakan Saferon Chewable Tablets

- Bila tidak boleh menggunakan

- Jangan menggunakan Saferon chewable tablet sekiranya:
 - anda alah (hipersensitif) kepada aspartame atau kepada sebarang bahan lain yang terkandung di dalam ubat ini.
 - anda adalah phenylketouric kerana produk ini mengandungi aspartame.

- Sebelum menggunakan Saferon Chewable Tablet

- Sila dapatkan nasihat doktor atau ahli farmasi anda jika anda hamil, merancang untuk hamil atau menyusu sebelum

menggunakan sebarang ubat. Saferon Chewable Tablets tidak boleh diambil pada trimester pertama kehamilan dan semasa penyusuan.

- Jika mengambil ubat-ubat lain

- Beritahu doktor jika anda mengambil sebarang ubat lain, termasuk ubat yang dibeli tanpa preskripsi dari farmasi, pasaraya, atau kedai makanan kesihatan.

Cara menggunakan Saferon Chewable Tablets

- Berapa banyak harus digunakan

- Ikut arahan doktor atau ahli farmasi anda. Ia mungkin berbeza dari maklumat di dalam risalah ini. Jika anda tidak memahami arahan pada label ubat anda, sila rujuk kepada doktor atau ahli farmasi.

Menggunakan ubat ini dengan mengunyah atau menelan keseluruhan tablet:

- Dewasa: 1 hingga 3 tablet setiap hari

- Bila perlu digunakan

- Ambil Saferon chewable tablet dalam dos berbahagi atau sekaligus atau ikut arahan doktor atau ahli farmasi anda.
- Ia perlu diambil semasa atau sejurus selepas makan

- Berapa lama perlu digunakan

- Teruskan penggunaan Saferon Chewable Tablets selama 3 hingga 5 bulan atau mengikut tempoh masa yang ditetapkan oleh doktor anda.

- Jika anda terlupa menggunakan

- Rujuk doktor atau ahli farmasi anda tentang perkara yang perlu anda lakukan jika anda terlupa menggunakannya.

- Ambil dos yang terlepas sebaik sahaja anda ingat. Sekiranya sudah hampir masa untuk dos seterusnya, abaikan dos yang tertinggal dan kemudian teruskan mengambil ubat mengikut jadual seperti biasa. Jangan ambil dos berganda untuk menggantikan dos yang terlepas.

- Jika mengambil berlebihan (terlebih dos)

- Hubungi doktor anda dengan segera atau pergi ke Jabatan Kecemasan hospital terdekat anda, jika anda fikir anda atau orang lain mungkin telah menggunakan dos berlebihan. Lakukan ini walaupun tiada tanda-tanda ketidakselesaan atau keracunan. Anda mungkin memerlukan perhatian perubatan segera.

Semasa menggunakan Saferon Chewable Tablets

- Perkara yang perlu dilakukan

- Guna ubat anda mengikut arahan doktor.
- Beritahu semua doktor, doktor gigi dan ahli farmasi yang merawat anda bahawa anda sedang menggunakan Saferon Chewable Tablets.

- Perkara yang tidak boleh dilakukan

- Jangan berhenti menggunakan ubat kecuali dinasihatkan oleh doktor anda.
- Jangan gunakan sebarang ubat baru tanpa berbincang dengan doktor atau ahli farmasi anda.
- Jangan berikan Saferon Chewable Tablets kepada orang lain, walaupun mereka mempunyai simptom atau keadaan yang sama seperti anda.

- Perkara yang perlu diberi perhatian

- Memandu dan menggunakan mesin

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Ubat ini mungkin mengganggu keupayaan anda untuk memandu atau mengendalikan mesin. Jika tablet menyebabkan anda terasa loya, pening atau letih, atau sakit kepala, jangan memandu atau mengendalikan mesin dan hubungi doktor anda dengan segera.

Kesan-kesan sampingan

- Loya, muntah, cirit-birit & sembelit berlaku tetapi jarang.

- Anda boleh melaporkan sebarang kesan sampingan atau kesan advers ubat kepada Pusat Pemantauan Kesan Advers Ubat Kebangsaan melalui laman web npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Cara penyimpanan dan pelupusan Saferon Chewable Tablets

- Penyimpanan

Simpan di bawah 25°C. Lindungi daripada kelembapan & cahaya. Jauhi ubat daripada kanak-kanak.

- Pelupusan

Ubat tidak harus dilupuskan melalui sisa air atau buangan isi rumah. Sila rujuk kepada ahli farmasi anda mengenai cara yang betul untuk melupuskan ubat yang tidak diperlukan lagi. Langkah-langkah ini dapat membantu melindungi alam sekitar.

Maklumat lanjut

- Rupa dan warna produk

Tablet tidak bersalut yang berwarna coklat berbintik-bintik, dwicembung, berbentuk bulat, dengan perisa coklat dan rasa manis.

- Bahan-bahan kandungan

- Bahan aktif

Setiap tablet mengandungi *Iron (III)-Hydroxide polymaltose complex* bersamaan dengan 100mg zat besi dan 500mcg *Folic acid*.

- Bahan tidak aktif

Lactose, Colloidal Silicon Dioxide, Ethyl Cellulose 7cps, Sucrose, Mannitol, Dextrose Anhydrous, Cocoa Powder, Aspartame, Methyl Parahydroxybenzoate, Propyl Hydroxybenzoate, Sodium Starch Glycolate, Croscarmellose Sodium, Isopropyl alcohol, Purified talc, Vanilex Special-DG35301, Methylene chloride, Trusil Chocolate Special, Purified Water, Magnesium Stearate and Povidone.

- Nombor MAL:

MAL06030848X

Pengilang

Glenmark Pharmaceuticals Ltd,
Plot No. E-37, 39, D-Road MIDC,
Satpur, Nasik - 422 007,
Maharashtra State, India

Pemegang Pendaftaran

Produk

Glenmark Pharmaceuticals (Malaysia) Sdn. Bhd.(660397-W)
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59200 Kuala Lumpur,
Malaysia

Tarikh kemaskini RiMUP

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Nombor Siri

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