菲普利

产品类型：抗贫血药

通用名称：蛋白琥珀酸铁口服溶液

商品名称：菲普利®

产品规格：15ml:40mg（以铁计））

主要成份：蛋白琥珀酸铁 800 毫克

（相当于三价铁 40 毫克）

医疗用途：绝对和相对缺铁性贫血的治疗

不良反应：略

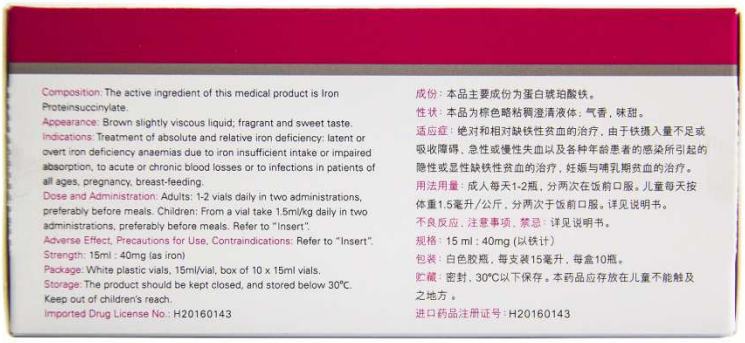
产品介绍

性状：本品为棕色略粘稠澄清液体；气香，味甜。
适应症：绝对和相对缺铁性贫血的治疗，由于铁摄入量不足或吸收障碍、急性或慢性失血以及各种年龄患者的感染所引起的隐性或显性缺铁性贫血的治疗，妊娠与哺乳期贫血的治疗。
用法用量：本品均由口服。
成人：每天 1-2 瓶（相当于三价铁 40-80 毫克），遵医嘱分两次在饭前口服。
儿童：每天按体重 1.5 毫升/公斤（相当于每天三价铁 4 毫克/公斤体重），应遵嘱分两次于饭前口服。

产品图片


中国药品电子监管码
蛋白琥珀酸铁口服溶液
Iron Proteinsuccinylate Oral Solution
15ml : 40mg (以铁计), 每盒10瓶
15ml : 40mg (as iron), box of 10 vials
菲普利® FERPLEX® 菲普利® FERPLEX® 菲普利® FERPLEX®


FERPLEX® 菲普利® FERPLEX® 菲普利® FERPLEX® 菲普利®
蛋白琥珀酸铁口服溶液
Iron Proteinsuccinylate Oral Solution
进口药品注册证号
Imported Drug License No. : H20160143
生产企业：
意大泛马克大药厂
ITALFARMACO, S.A.
地址：San Rafael, 3 28108 Alcobendas (Madrid) Spain


Composition: The active ingredient of this medical product is Iron Proteinsuccinylate.
Appearance: Brown slightly viscous liquid; fragrant and sweet taste.
Indications: Treatment of absolute and relative iron deficiency: latent or overt iron deficiency anaemias due to iron insufficient intake or impaired absorption, to acute or chronic blood losses or to infections in patients of all ages, pregnancy, breast-feeding.
Dose and Administration: Adults: 1-2 vials daily in two administrations, preferably before meals. Children: From a vial take 1.5ml/kg daily in two administrations, preferably before meals. Refer to "Insert".
Adverse Effect, Precautions for Use, Contraindications: Refer to "Insert".
Strength: 15ml : 40mg (as iron)
Package: White plastic vials, 15ml/vial, box of 10 x 15ml vials.
Storage: The product should be kept closed, and stored below 30℃. Keep out of children's reach.
Imported Drug License No.: H20160143
成份：本品主要成份为蛋白琥珀酸铁。
性状：本品为棕色略粘稠澄清液体；气香，味甜。
适应症：绝对和相对缺铁性贫血的治疗，由于铁摄入量不足或吸收障碍，急性或慢性失血以及各种年龄患者的感染所引起的隐性或显性缺铁性贫血的治疗，妊娠与哺乳期贫血的治疗。
用法用量：成人每天1-2瓶，分两次在饭前口服。儿童每天按体重1.5毫升/公斤，分两次于饭前口服。详见说明书。
不良反应，注意事项，禁忌：详见说明书。
规格：15 ml : 40mg (以铁计)
包装：白色胶瓶，每支装15毫升，每盒10瓶。
贮藏：密封，30℃以下保存。本药品应存放在儿童不能触及之地方。
进口药品注册证号：H20160143


FERPLEX® 菲普利® FERPLEX® 菲普利® FERPLEX® 菲普利®
蛋白琥珀酸铁口服溶液
Iron Proteinsuccinylate Oral Solution
生产企业：
意大泛马克大药厂
ITALFARMACO,S.A.


FERPLEX® 菲普利®
蛋白琥珀酸铁口服溶液
Iron Proteinsuccinylate Oral Solution
产品批号 Batch No.:
生产日期 Mfg. Date:
有效期至 Exp. Date:
蛋白琥珀酸铁口服溶液
Iron Proteinsuccinylate Oral Solution


14897046740082

说明书

核准日期：2016年2月29日
修改日期：2016年4月21日

菲普利®

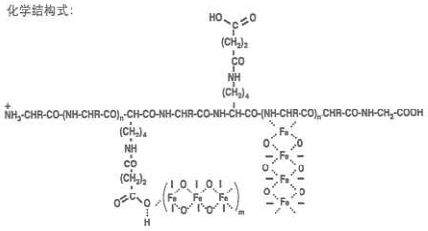
蛋白琥珀酸铁口服溶液说明书

（请仔细阅读说明书并在医师指导下使用）

【药品名称】
通用名称：蛋白琥珀酸铁口服溶液
商品名称：菲普利®
英文名称：Iron Proteinsuccinylate Oral Solution
汉语拼音：Danbaihuposuan Tie Koufurongye

【成份】
本品主要成份为蛋白琥珀酸铁800毫克（相当于三价铁40毫克）

化学结构式：



分子量：5000 KD

【性状】
本品为棕色略粘稠澄清液体；气香，味甜。

【适应症】
绝对和相对缺铁性贫血的治疗，由于铁摄入量不足或吸收障碍、急性或慢性失血以及各种年龄患者的感染所引起的隐性或显性缺铁性贫血的治疗，妊娠与哺乳期贫血的治疗。

【规格】
15ml：40mg（以铁计）

【用法用量】
本品均由口服。
成人：每天1-2瓶[相当于三价铁40-80毫克]，遵医嘱分两次在饭前口服。
儿童：每天按体重1.5毫升/公斤[相当于每天三价铁4毫克/公斤体重]，应遵医嘱分两次于饭前口服。

【不良反应】
与其他药物一样，本品也可能导致不良反应，但并非所有患者都会出现这些反应。
以下不良反应已有报告（频率未知）：
胃肠道病症：胃痛、恶心、呕吐、便秘、腹泻，在减量或停药后可迅速消退。
皮肤和皮下组织病症：过敏反应。
由于铁的排泄，可能会出现绿色或黑色便。此反应无害。
若认为出现了严重的不良反应，或发现了本说明书中未提到的不良反应，请告知医生或药剂师。

【禁忌】
下列情况不得服用本品：
- 对蛋白琥珀酸铁或药物中其他成分过敏；
- 对乳蛋白过敏；
- 患有会导致体内铁蓄积的疾病（血色病，含铁血黄素沉着症）；
- 患有由铁蓄积所引起的胰腺炎（胰腺炎症）或肝硬化（以改变结构和正常功能的纤维变性或肝组织瘢痕形成为特征的慢性肝病）；
- 患有缺铁以外原因导致的贫血（包括再生障碍性贫血、溶血性贫血、铁利用障碍性贫血等）。

【注意事项】
在开始治疗前，应先找出产生贫血的原因。本品尤其适用于妊娠与哺乳期妇女贫血的治疗。本品不会影响病人的反应（驾驶及机器的操作）。本品不会引起成瘾性，除了持续性出血、月经过多及怀孕外，不应服用本品超过六个月。

【孕妇及哺乳期妇女用药】
本品适用于妊娠与哺乳期妇女贫血的治疗。

【儿童用药】
儿童每天按体重1.5毫升/公斤[相当于每天三价铁4毫克/公斤体重]，应遵医嘱分两次于饭前口服。

【老年用药】
本品未进行老年用药相关试验研究，但预计不存在限制本品在老人使用的特殊问题。

【药物相互作用】
若正在服用或近期曾服用其他药物（包括未经处方获得的药物），需告诉医师或药剂师。本品可能会减弱肠吸收，因此降低了下列药物的有效性：
1. 喹诺酮类和四环素类抗生素；
2. 双膦酸盐，用于骨质疏松症（骨质流失和脆弱）；
3. 青霉胺，用于治疗关节炎（关节炎症）；
4. α-甲基多巴，用于治疗动脉压过高（高血压）；
5. 甲状腺素，用于治疗甲状腺功能减退（甲状腺激活不足）；
6. 左旋多巴和卡比多巴合剂，用于治疗帕金森病；
7. 麦考酚酸吗乙酯，用于预防移植排斥。

由于肠道内铁吸收，与下列药物同时服用时可能会降低FERPLEX的有效性。因此下列药物与本品之间的给药间隔应至少为2小时：
1. 抗酸药，用于胃酸患者；
2. 氯霉素（抗生素）；
3. 用于治疗胃溃疡和食管反流的药物，如奥美拉唑、兰索拉唑、泮托拉唑。

服用超过200毫克维生素C可增加铁质的吸收。

【药物过量】
服用大量补铁药物后6至8小时会产生上腹部疼痛、恶心、呕吐、腹泻及呕血，亦可产生嗜睡、面色苍白、青黑斑、休克甚至昏迷。可立即服用催吐药后再洗胃以作治疗。

【药理毒理】
本品中的铁与乳剂琥珀酸蛋白结合，形成铁-蛋白络合物，用以治疗各种缺铁性贫血症。

【药代动力学】
本品是一种有机铁化合物，它在酸碱度pH值小于4时能呈沉淀物，而在酸碱度pH较高时(pH 7.5-8)又重新变为可溶性物质。此外，该制剂不被胃蛋白酶消化，却在中性pH值时可被胰蛋白酶水解。

由于蛋白琥珀酸铁的这些性质，本药品所含的铁受蛋白膜的保护而不同胃液中盐酸和胃蛋白酶发生反应，因此，该制剂不会造成胃黏膜损伤。本品中的铁在十二指肠内开始释放，特别应在空肠中释放，因为正常pH值的升高使得这种化合物重新变得可溶，并且使蛋白膜为胰蛋白酶所消化。

这样的铁非常有利于机体的生理吸收，却又不会形成太高的吸收峰；事实上，它呈现一种恒定的吸收趋势，在机体的各个部位逐渐达到吸收与贮存的最佳平稳状态。因此，本品一般不会产生胃肠的耐受性问题。

【贮藏】
密封，30℃以下保存。本药品应存放在儿童不能触及之地方。

【包装】
白色胶瓶，每支装15毫升，每盒10瓶。

【有效期】
24个月

【执行标准】
进口药品注册标准JX20150308

【批准文号】
进口药品注册证号H20160143

【生产企业】

意大泛马克大药厂
ITALFARMACO,S.A.

ITALFARMACO S.A.
生产地址 ：San Rafael,3 28108 Alcobendas (Madrid) Spain
邮政编码 ：28108
电话号码 ：34-91-657-2323
传真号码 ：34-91-657-2372
网　　址 ：www.italfarmaco.com

【中国联络企业】

LEE'S PHARM.
李 氏 大 藥 廠

李氏大药厂（香港）有限公司
地　　址 ：香港沙田香港科学园科技大道西二号生物资讯中心110-111室
电话号码 ：852-2314-1282
传真号码 ：852-2314-1708
网　　址 ：www.leespharm.com

Date of Approval : 2016.02.29
Date of Revision : 2016.04.21

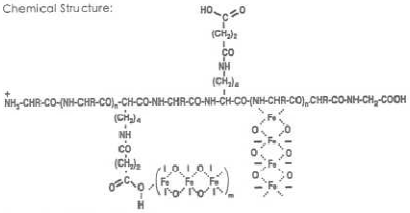
Iron Proteinsuccinylate Oral Solution

Please read carefully this insert before use, as directed by doctors

【Name of Drug】
Generic Name : Iron Proteinsuccinylate Oral Solution
Brand Name : FERPLEX®
Product Name : Iron Proteinsuccinylate Oral Solution
Chinese Pronunciation : Danbaihuposuan Tie Koufurongye

【Composition】
The active ingredient of this medical product is Iron Proteinsuccinylate 800mg (Equivalent to 40mg of Trivalent Iron)

Chemical Structure:



Molecular Weight: 5000 KD

【Appearance】
Brown slightly viscous liquid; fragrant and sweet taste.

【Indications】
Treatment of absolute and relative iron deficiency: latent or overt iron deficiency anaemias due to iron insufficient intake or impaired absorption, to acute or chronic blood losses or to infections in patients of all ages, pregnancy, breast-feeding.

【Strength】
15ml : 40mg (as Iron)

【Dose and Administration】
FERPLEX® is taken orally.
Adults: 1-2 vials (equivalent to 40-80mg of trivalent iron) daily upon doctor's prescription in two administrations, preferably before meals.
Children: From a vial take 1.5ml/kg daily (equivalent to 4mg/kg daily of trivalent iron) upon doctor's prescription in two administrations, preferably before meals.

【Adverse Effect】
Like all medicines, FERPLEX 40 mg oral solution can cause adverse effects, but not all patients will experience them.
The following adverse effects have been reported (frequency unknown):

Gastrointestinal disorders: stomach pain, nausea, vomiting, constipation or diarrhoea, which may disappear quickly after reducing the dose or after discontinuing the treatment, if appropriate.

Skin and subcutaneous tissue disorders: allergic reactions.
Appearance of green or black faeces, due to the elimination of iron. This adverse effect is harmless.
If you think that any of the adverse effects you are suffering from is serious or if you detect any adverse effects not mentioned in this insert, tell your doctor or pharmacist.

【Contraindications】
Do not take FERPLEX 40 mg oral solution:
- If you are allergic (hypersensitive) to iron protein succinylate or to any other component of this medicine, don't take this medicine.
- If you are allergic to milk proteins, don't take this medicine.
- If you suffer from any disease that causes accumulation of iron in the body (haemochromatosis, haemosiderosis) , don't take this medicine.
- If you suffer from pancreatitis (inflammation of the pancreas) or hepatic cirrhosis (chronic liver disease characterized by the formation of fibrosis or "scarring" of liver tissue that changes its structure and normal function) due to iron accumulation, don't take this medicine.
- If you suffer from anaemia due to causes other than iron deficiency (including aplastic, haemolytic and sidero-achrestic anaemias).

【Precautions for Use】
In case of anemia, establish its cause before treatment. There are no special warnings during pregnancy or breast-feeding, because Ferplex is particularly indicated in the iron deficiencies which may occur in such conditions. No effect on patient's reactions (driving, operation machinery) are known. No special warnings are required concerning addiction or dependence risks. However, the administration of Ferplex should not exceed 6 months, unless in case of continued haemorrhagia, menorrhagia or pregnancy.

【Use in Pregnant & Lactating Women】
Indicated for iron deficiency anaemias in pregnant and lactating women.

【Use in Children】
Use 1.5ml/kg body weight daily (equivalent to 4mg/kg body weight daily of trivalent iron) upon doctor's prescription in two administrations, preferable before meals.

【Use in Elderly】
No studies have been performed for iron proteinsuccinylate in elderly. It is expected that the drug can be used in elderly patients.

【Interactions】
Tell your doctor or pharmacist if you are using or have recently used other medicines, including those obtained without a prescription.

FERPLEX 40 mg oral solution can reduce intestinal absorption and therefore the effect of some medicines such as:
1. Antibiotics such as quinolones and tetracyclines.
2. Bisphosphonates, used in patients with osteoporosis (loss and weakening of the bones).
3. Penicillamine, used for arthritis (inflammation of the joints).
4. Alpha-methyldopa, used to treat arterial hypertension (high blood pressure).
5. Thyroxine, used for the treatment of hypothyroidism (underactive thyroid gland).
6. Levodopa and carbidopa, used for the treatment of Parkinson's disease.
7. Mycophenolate mofetil, used to prevent transplant rejection.

Intestinal absorption of iron and therefore the efficacy of Ferplex 40 mg oral reduced if taken together with the medicines listed below, so you should wait at least 2 hours between taking any of these medicines and taking Ferplex:
1. Antacids, normally used in patients suffering from gastric acidity.
2. Chloramphenicol (antibiotic).
3. Medicines for the treatment of stomach ulcer or oesophageal reflux such as omeprazole, lansoprazole, pantoprazole.

Taking more than 200mg of Vitamin C may enhance the absorption of iron.

【Overdose】
During the first 6-8 hours from intake of massive doses of iron drugs, epigastric pain, nausea, vomiting, diarrhoea and haematemesis may occur, somnolence, paleness, livor, shock and coma may also occur. Recommended treatment is the immediate administration of an emetic, followed by gastric lavage and adequate supporting therapy.

【Pharmacology & Toxicology】
This is a patented medicinal product in which the iron is bound to milk succinylated proteins to form an iron-protein complex, used for treatment of all the sideropenic anaemias.

【Pharmacokinetics】
This organic iron compound has a noticeable physicochemical property: its insolubility in an acid environment (<pH 4) and its ability to dissolve in a slightly alkaline environment (pH 7.5-8). Besides, the preparation is not digested by the pepsin while is hydrolyzed by the pancreatin at neutral pH.

Due to these characteristics, the iron contained in product is protected by the proteic shell from the actions of hydrochloric acid and pepsin of the gastric juice: as a result, it does not cause gastric mucosal damage which is common to most of iron salts, especially those in ferrous form. The delivery of iron from product occurs lately in the duodenal lumen and, above all, in the jejenum as a consequence of the normal pH raises which makes the compound soluble again and allow the digestion of the proteic shell by the pancreatic enzymes.

So, the iron becomes available for the physiologic absorption without reaching too high peaks, in fact, with a constant trend an excellent plateau for the absorption and the storage in the sites of the body is gradually reached. The product does not generally cause gastrointestinal intolerance troubles.

【Storage】
The product should be kept closed, and stored below 30°C. Keep out of children's reach.

【Package】
White plastic vials, 15ml/vial, box of 10 x 15 ml vials.

【Shelf Life】
24 months

【Approval Specification】
Imported Drug Specification No.JX20150306

【Approval License】
Imported Drug License No.H20160143

【Manufacturer】

意大泛马克大药厂
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【China Contact Enterprise】

LEE'S PHARM.
李氏大藥廠

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