

Fer Plus®

Complexe d'hydroxyde de polymaltose de Fer 232 mg
(correspondant à 71 mg de Fe³⁺ par 5 ml)

Solution buvable

1/ Identification du médicament :

Composition :

Pour 5 ml (soit 71 mg de Fe³⁺)

Principe actif :

Complexe d'hydroxyde de fer(III)-polymaltose...232mg

Excipients :

Sorbitol Solution à 70%, saccharose, parahydroxybenzoate de méthyle, parahydroxybenzoate de propyle, essence de citron, eau purifiée q.s.p 5 ml.

Forme pharmaceutique : Solution buvable.

Classe pharmaco-thérapeutique : Antianémique. Hydroxyde de fer par voie orale (B : sang et organes hématopoïétiques).

2/ Dans quel cas utiliser ce médicament ?

Traitements préventif et curatif des manifestations des carences en fer, en particulier : anémie due à une carence en fer, ou besoin d'un apport accru en fer, surtout pendant la grossesse et l'allaitement, chez le prématuré, les enfants et après des épisodes hémorragiques.

3/ Attention :

Dans quel cas ne pas utiliser ce médicament ?

- Hypersensibilité connue au principe actif ou à l'un des excipients.
- Anémie non due à un manque en fer.
- Affection rare caractérisée par une surcharge en fer des tissus de l'organisme (stockage excessif de fer).
- Troubles de l'utilisation du fer.

En cas de doute, il est indispensable de demander l'avis de votre médecin ou de votre pharmacien.

Mises en garde spéciales et précautions d'emploi :

- Les anémies devraient toujours être traitées sous contrôle médical.
- En cas d'inefficacité du traitement (pas d'élévation du taux d'hémoglobine d'environ 2 à 3g/dl de sang en 3 semaines), ce dernier doit être revu par votre médecin.

- La prudence est de mise chez les patients recevant des transfusions sanguines répétées car un apport de fer concomitant à celui d'érythrocytes peut provoquer une surcharge en fer.

- Ne pas laisser à la portée des enfants.

- En raison de la présence de saccharose et de sorbitol, l'utilisation de ce médicament est déconseillée chez les patients présentant une intolérance au fructose, un syndrome de malabsorption du glucose et du galactose ou un déficit en sucrose / isomaltase (maladies héréditaires rares)

-Ce médicament contient 750mg de saccharose par unité de prise (7,5ml) dont il faut tenir compte dans la ration journalière en cas de régime pauvre en sucre ou en cas de diabète.

-Ce médicament contient du "parahydroxybenzoate de méthyle" et du "parahydroxybenzoate de propyle" et peut provoquer des réactions allergiques.

Grossesse et allaitement :

C'est précisément au cours de ces périodes qu'une carence en fer peut se manifester. La solution buvable FER PLUS devrait cependant être uniquement prise sur consultation d'un médecin. Au cours des 3 premiers mois de la grossesse, l'apport de fer à votre organisme est en général suffisant si votre régime est équilibré. Afin de couvrir le besoin accru en fer de l'enfant en phase de développement, votre médecin peut vous prescrire une préparation à base de fer.

Demandez conseil à votre médecin ou à votre pharmacien avant de prendre tout médicament.

Effets sur l'aptitude à conduire des véhicules ou à utiliser des machines :

L'utilisation de FER PLUS solution buvable n'engendre pas de risque à conduire des véhicules ou à utiliser des machines

Liste des excipients dont la connaissance est nécessaire pour une utilisation sans risque chez certains patients :

Saccharose, sorbitol, parahydroxybenzoate de méthyle, parahydroxybenzoate de propyle.

4/ Comment utiliser ce médicament ?

Posologie :

**Traitement curatif:

Age	Dose en mg/j	Dose journalière
Nourrisson jusqu'à 1 an	35,5 à 71	2,5 à 5 ml
De 1 à 12 ans	71 à 106,5	5 à 7,5 ml
Adolescent de plus de 12 ans et adulte	106,5 à 284	7,5 à 20 ml

فير بلوس®

مركب من هيدروكسيد الحديد-هيمالطوز 232 مغ
(ما يعادل 71 مغ حديد Fe³⁺ 5 مل)
محلول للشرب

1/ التعريف بالدواء:

المكونات:

5 مل (71مغ من فير 3+)

المادة الفعالة:

مركب من هيدروكسيد الحديد و البوليملتوز

الأسوية:

محلول الصوريبتول ب 70% ، سكروز، ميتيل بارابين، بروبيل بارابين، زيت الليمون، ماء مصفى ككل 5مل.

الشكل الصيدلاني: محلول للشرب

الفئة الدوائية: مكافح لفقر الدم. هيدروكسيد الحديد سبيل قموي ا:ب: الدم و أعضاء تكوين الدم

2/في أي حالة يستعمل هذا الدواء؟

وقاية و علاج مظاهر نقص الحديد و خاصة: فقر الدم المنجر عن نقص الحديد أو حاجة متزايدة للحديد و خصوصا خلال فترة الحمل و الرضاعة، عند الأطفال الخدج و الأطفال و بعد النزيف.

3/تحذير:

في أي حالة لا يجب استعمال هذا الدواء؟

-حساسية للجوهر الفعال أو لإحدى الأسوية
-فقر الدم الغير منجر عن نقص في الحديد
-علة نادرة تتمثل في حمولة زائدة من الحديد في أنسجة الجسم (التخزين المفرط للحديد)

-اضطرابات في استخدام الحديد

في حالة شك لا تتردد في أخذ رأي طبيبك أو صيدليكم

احتياطات الإستعمال:

-ينبغي معالجة حالة فقر الدم دائما تحت إشراف طبي.
-في حالة عدم فعالية العلاج (عدم ارتفاع معدل الهيموغلوبين في الدم بحوالي 2 الى 3غ/دسل طيلة 3 أسابيع، يجب إعادة النظر فيه من قبل الطبيب.

-يجب توخي الحذر لدى المرضى الذين يتلقون نقل الدم بصفة متكررة لأن كمية الحديد المصاحبة للكريات الحمراء تؤدي الى ارتفاع نسبة الحديد

-يحفظ بعيدا عن متناول الأطفال

-نظرا لتواجد السكروز و السوربيتول، يجب عدم استعمال هذا الدواء في حالة عدم التحمل للفركتوز أو متلازمة سواء إمتصاص الغلوكوز والفلاكتوز أو مرض عوز الأنزيم سوكراز إزومالتاز (مرض وراثي نادر)

-هذا الدواء يحتوي على 750 مغ من السكروز في 7,5 مل يجب الإنتباه إلى الوجبة اليومية خاصة في حالة حمية بدون سكر أو مرض السكري.

-يحتوي هذا الدواء على بروبيل بارابين و بروبيل بارابين، مما يمكن أن ينجر عنه تفاعلات أرجية.

الحمل والرضاعة:

خديدا في هذه الفترة يبرز نقص الحديد الا انه لا يمكن تناول هذا الدواء دون استشارة الطبيب.

عادة ما تكون كمية الحديد المتأنية من تغذية متوازنة. خلال الثلاث أشهر الأولى من الحمل كافية لتغطية الحاجة المتزايدة من الحديد في مرحلة نمو الجنين. قد يصف لكم الطبيب مستحضر من الحديد.

يجب استشارة طبيبك أو صيدليكم قبل تناول اي دواء تأثير في القدرة على القيادة أو على استخدام الآلات:

تناول فير بلوس محلول للشرب لا يولد أي مخاطر عند قيادة السيارة أو استخدام الآلات.

قائمة الأسوية التي يجب معرفتها لاستعمال آمن لدى بعض المرضى:

سكروز، سوربيتول، ميتيل بارابين، بروبيل بارابين.

4/ كيفية استعمال هذا الدواء؟

المقادير:

****استعمال علاجي:**

العمر	الجرعة بالغ في اليوم	الجرعة اليومية
رضيع الى غاية سنة	35,5 الى 71	2,5 مل الى 5مل
من سنة الى 12 سنة	71 الى 106,5	5 مل الى 7,5 مل
مراهق اكبر من 12 سنة و كهل	106,5 الى 284	7,5 مل الى 20 مل

Fer Plus®

Iron hydroxide polymaltose complex 232 mg
(corresponding to 71 mg of Fe³⁺ by 5 ml)

Oral solution

1/ Identification of the drug :

Composition :

For 5 ml (71 mg of Fe³⁺)

Principe actif :

Iron(III) hydroxide polymaltose complex 232 mg

Excipients :

Sorbitol solution at 70%, sucrose, methyl parahydroxybenzoate, propyl parahydroxybenzoate, lemon essence, purified water s.q.f 5ml.

Pharmaceutical form : Oral solution.

Pharmacotherapeutical class : Antianemic. Iron hydroxyde by oral route (B : Blood and hematopoietic organs).

2/ When to use this medicine ?

Treatment of the latent states or manifestations of iron deficiency, in particular: anemia due to an iron deficiency, or to an increased need for iron, especially during pregnancy and breastfeeding, in premature, infants, children and after haemorrhagic episodes.

3/ Warnings :

In which cases DO NOT use this medicine ?

- Known hypersensitivity to the active substance or to any excipient
- Anemia not due to a lack of iron.
- A rare condition characterized by iron overload of tissues in the body (excessive storage of iron).

- Disorders of iron utilization.

In case of doubt, it is necessary to ask your doctor or pharmacist for advice.

Special warnings and precautions for use :

- The anemia should always be treated under medical supervision.
- In case of lack of efficiency (no rise in hemoglobin of about 2 to 3 g/dl of blood in 3 weeks), the treatment must be reviewed by your doctor.

- Pay attention in patients receiving repeated blood transfusions because an intake of iron concomitant to that of erythrocytes can lead to an iron overload.

- Keep away from the reach of children.

-Due to the presence of sucrose and sorbitol; the use of this medicine is not recommended in patients with intolerance to fructose, a syndrome of glucose or galactose malabsorption, or sucrose isomaltase deficit (rare hereditary diseases)

-This drug contains 750mg of sucrose per intake unit (7,5 ml) which must be considered in the daily ration in case of diet low in sugar or diabetes.

-This drug contains methyl and propyl parabens and may induce allergic reactions.

Pregnancy and breastfeeding :

It is precisely during these periods that iron deficiency may manifest. However, FER PLUS oral solution should only be taken on medical advice

During the first 3 months of pregnancy, iron intake for your body is usually enough if your diet is balanced. To cover the increased need for iron of the child in the development phase, your doctor may prescribe a preparation of iron.

Ask your doctor or pharmacist for advice before using any medicine.

Effects on the ability to drive and use machines

The use of FER PLUS oral solution does not create risk to driving or operating machinery.

List of excipients whose knowledge is necessary for a safe use in certain patients : Sucrose, sorbitol, methyl parahydroxybenzoate and propyl parahydroxybenzoate.

4/ How to use this medicine ?

Dosage :

**** Curative treatment:**

Age	Dose in mg/day	Daily dose
Infant up to 1 year	35,5 to 71	2,5 to 5 ml
From 1 to 12 years	71 to 106,5	5 to 7,5 ml
Teenager over 12 years and adult	106,5 to 284	7,5 to 20 ml

****Traitement préventif:**

Age	Dose en mg/j	Dose journalière
De 1 à 12 ans	35,5 à 71	2,5 à 5 ml
Adolescent de plus de 12 ans	71 mg	2,5 ml x 2
Adulte	106,5	7,5 ml en une seule prise

***Prématurés :** 2,5 – 5 mg de fer par kilo de poids corporel, tous les jours pendant 3 à 5 mois.
Après rétablissement des paramètres normaux (hémoglobine, hématocrite, érythrocyte), le traitement devra être poursuivi afin de restaurer les réserves de fer.

Mode et voie d'administration

Voie orale.

Symptômes et instructions en cas de surdosage :

En cas de surdosage, aucune intoxication ou surcharge en fer n'a été observée jusqu'à présent. En effet, le fer contenu dans le complexe d'hydroxyde de fer(III)-polymaltose ne se trouve pas dans le tractus gastro-intestinal sous forme de fer libre et n'est pas absorbé dans l'organisme par diffusion. Les symptômes connus avec d'autres préparations de fer (sels de fer(III)) tels que : chute de la tension artérielle, état de choc, acidose métabolique, coma ou convulsions/crampes n'ont pas été rapportés à ce jour avec les préparations à base de complexe d'hydroxyde de fer III polymaltose.

5/ Quels sont les effets indésirables éventuels ?

Occasionnellement, en cas de doses thérapeutiques très élevées, des troubles gastro-intestinaux peuvent apparaître tels que: crampes abdominales, nausées, vomissement et diarrhées.

Très rarement, il se manifeste des réactions allergiques (asthme, urticaire) et des réactions cutanées localisées (prurit, rash).

Il se manifeste fréquemment une coloration des selles due à l'élimination de fer. Rarement, une coloration foncée des urines a été observée. L'apparition d'une éventuelle coloration des dents est insignifiante et réversible.

Ces effets indésirables sont en général bénins et passagers.

Si vous remarquez des effets indésirables non mentionnés dans cette notice, ou si certains effets indésirables deviennent graves, veuillez en informer votre médecin ou votre pharmacien.

6/ Comment conserver ce médicament ?

A conserver à une température ne dépassant pas 30 °C.

A.M.M. N° : Flacon de 60 ml: 902 376 1

A.M.M. N° : Flacon de 250 ml: 902 376 2

Date de révision de la notice : Février 2023

****استعمال وقائي:**

العمر	الجرعة البالغ في اليوم	الجرعة اليومية
من سنة الى 12 سنة	35,5 الى 71	2,5 الى 5مل
مراهق اكبر من 12 سنة	71مغ	2,5 مل x 2
كهل	106,5	7,5 مل على مرة واحدة

****استعمال لدى الرضيع ذو الولادة المبكرة:** 2,5- 5 - مغ من الحديد/كغ من وزن الجسم. يوميا. لمدة 3-5 أشهر.
بعد تعديل المعالم الطبيعية (الهيموغلوبين, الهيماتوكريت, كرات الدم الحمراء). ينبغي مواصلة العلاج من أجل استعادة مخزون الحديد.
كيفية و سبيل الاستعمال:

سبيل فموي

الأعراض والإرشادات في حالة الإفراط في الجرعة:

في حالة الإفراط في الجرعة. لم تلاحظ أية حالة تسمم أو حمولة زائدة من الحديد إلى حد الآن. في الواقع, ان الحديد المحتوي في مركب هيدروكسيد الحديد و البوليملتوز لا يتواجد على شكل حديد حر في الجهاز الهضمي و لا يتم استيعابه في الجسم عن طريق الانتشار, الاعراض العروفة و المنجرة عن تناول مستحضرات أخرى من الحديد (املاح الحديد) مثلا: انخفاض ضغط الدم, حالة صدمة, حمض استقلابي, حالة غيبوبة او تشنجات. لم يتم الاخبار عن أي منها الى حد الآن.

5/ما هي التأثيرات الغير مرغوب فيها؟

أحيانا, في حالة العلاج بجرعات عالية. من الممكن ظهور اضطرابات في الجهاز الهضمي مثل: تشنجات عضلية, غثيان, تقيء, اسهال.

في حالات نادرة جدا يمكن ظهور تفاعلات أرجية (ربو, شرى) و تفاعلات جلدية محددة الموقع (حكاك, طفح).

عند تخلص الجسم من الحديد, عادة ما يحدث تلون في الغائطيات.

نادرا ما يحدث تلون في البول.

يمكن ظهور تلون في الأسنان, الا أنه يعتبر ذات أهمية محدودة و غالبا ما يكون قابلا للإعتكاس.

هذه التأثيرات الغير مرغوب فيها عادة ما تكون هينة و عرضية. ينبغي إبلاغ الطبيب أو الصيدلاني عن كل تأثير غير مرغوب فيه أو مزعج غير وارد ذكره في النشرة.

6/كيف يحفظ هذا الدواء؟

يحفظ في درجة حرارة لا تتجاوز 30 درجة مئوية

تأشيرة رقم: فأرورة سعة 60مل: 1 902 376

تأشيرة رقم: فأرورة سعة 250مل: 2 902 376

تاريخ مراجعة النشرة: فيفري 2023

**** Preventive treatment**

Age	Dose in mg/day	Daily dose
From 1 to 12 years	35,5 to 71	2,5 to 5 ml
Teenager over 12 years	71	2,5 ml x 2
Adult	106,5	7,5 ml in a single intake

***Prematures :** 2,5 – 5 mg of iron per kg of body weight, every day during 3 to 5 months.

After re-establishment of the normal parameters (haemoglobin, hematocrit, erythrocyte), the treatment must be maintained to restore the iron reserves.

Mode and route of administration

Oral route.

Symptoms and instructions in case of overdose :

In case of overdose, no poisoning or iron overload has been observed so far. Indeed, the iron in the complex of iron hydroxide (III)-polymaltose is not found in the gastrointestinal tract in the form of free iron and is not absorbed into the body by diffusion. Symptoms known to other iron preparations (iron(III) salts) such as low blood pressure, shock, metabolic acidosis, coma or convulsions / cramps have never been reported to date with preparations of iron III hydroxide polymaltose complex.

5/ What are the potential side effects ?

Occasionally, in case of very high therapeutic doses, gastro-intestinal disorders may appear such as : abdominal cramps, nausea, vomiting and diarrhoea.

Very rarely, allergic reactions (asthma, urticaria) and local cutaneous reactions (pruritis, rash) may manifest.

It occurs frequently a coloration of stool due to the elimination of iron. Rarely, dark urine was observed.

The appearance of any coloration of the teeth is insignificant and reversible.

These side effects are mild and transient.

If you notice side effects not mentioned in this leaflet, or if certain side effects become serious, inform your doctor or pharmacist.

6/ How to store this medicine ?

Do not store above 30 °C.

M.A. N° : Bottle of 60 ml: 902 376 1

M.A. N° : Bottle of 250 ml: 902 376 2

Leaflet's revision date : February 2023

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AC0865/V6

THIS IS A MEDICINE

- A medicine is a product, but not a product as others.
- A medicine is a product which affects your health, and its consumption contrary to instructions is dangerous.
- Comply strictly with the prescription and instruction of use as prescribed by your doctor.
- Follow the advice of your pharmacist.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not interrupt by your self the period of treatment prescribed for you.

Keep medicines out of the reach of children



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- Follow the advice of your pharmacist.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not interrupt by your self the period of treatment prescribed for you.

Keep medicines out of the reach of children



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