PACKAGE LEAFLET: INFORMATION FOR THE USER

POLY-IRON®
Ferrous gluconate (Fe^{++}) 300mg (37.5mg)/sachet
Powder for oral solution

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have further questions, ask you doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs or illness are the same as yours.
- If you get any side effect, talk to your doctor or pharmacist. This includes any possible side effect not listed in this leaflet.

What is in this leaflet:

1. What **POLY-IRON®** is and what is used for
2. What you need to know before you take **POLY-IRON®**
3. How to take **POLY-IRON®**
4. Possible side effects
5. How to store **POLY-IRON®**
6. Contents of the pack and other information

1. WHAT POLY-IRON® IS AND WHAT IS USED FOR

POLY-IRON® belongs to a group of medicines called iron supplements.
These medicines are acting by replacing iron in the body. Iron is necessary for the body in order to produce red blood cells.
When iron levels are not sufficient in the body, the levels of red blood cells are not enough to keep the body in a healthy condition. This condition is called anaemia due to iron insufficiency.
POLY-IRON® is used for the treatment of anaemia due to iron incufficiency.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE POLY-IRON®

Do not take POLY-IRON®:

• If you are allergic (hypersensitive) to ferrous gluconate or any of the other ingredients **POLY-IRON®** (See section 6)
• If you have anemia not caused by Iron deficiency, e.g. microcytic anemia
• If you have a build-up of too much iron in the body like hemochromatosis
• If you have severe liver inflammation (chronic pancreatitis, liver cirrhosis)
• If you receive regular blood transfusions
• If you have active peptic ulcer, enteritis or ulcerative colitis

Warnings and precautions

Talk to your doctor or pharmacist before taking **POLY-IRON®** if you have:
• hemolytic anemia
• blood disease (hemoglobin disease)

Other medicines and POLY-IRON®

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other

medicines. Especially if you take:
- tetracyclines (used for the treatment of bacterial infections)
- antacids, containing aluminum hydroxide or magnesium carbonate (used for the treatment of heartburn or gastroesophageal reflux)
- proton pump inhibitors and antagonists of H_2 receptors (used for the reductions of gastric acids' production)
- penicillamine (used for the treatment of rheumatoid arthritis)
- ascorbic acid (vitamin C)
- captopril and methyldopa (used for the treatment of high blood pressure and heart failure)
- antimicrobial agents of the group of quinolones (e.g. ciprofloxacin, norfloxacin, ofloxacin)
- thyroxin (thyroid hormone)
- chloramphenicol (used for the treatment of bacterial infections)
- levodopa, carbidopa (used for the treatment of Parkinson's disease)
- bisphosphonates (used in the treatment of osteoporosis)
- mycophenolate mofetil (an immunosuppressant medicine given after an organ transplantation)

Laboratory tests
The use of iron containing preparations may induce black stools and in large quantities can affect the tests used to detect blood in the stools.

POLY-IRON® with food and drink

POLY-IRON® should be taken half an hour before any meal. This will help the relief of sided effect that are related to stomach. However, it is not recommended to take your medicine together with tea, coffee, eggs or milk, as the effectiveness of the medicine might be reduced.
Alcohol in general enhances iron absorption.

Pregnancy, breast-feeding and fertility

If you are pregnant, or you breast-feed or your aplanning to have a baby, ask your doctor's or pharmacist's advice before you take this medicine.
POLY-IRON® may be used during pregnancy and breast-feeding.

Driving and using machines

No effects are known.

POLY-IRON® contain:

-fructose: If have been told you that you have intolerance in certain sugars, inform your doctor before you take this medicine.

3. HOW TO TAKE POLY-IRON®

Always take this medicine as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist it you are not sure. It is important to use your medicine regularly.

Adults and elderly:
Unless otherwise specified in a medical prescription:
Content of 2 sachetts, 1-3 times a day, diluted in water, half an hour before any meal, depending on the severety of anemia (according to lab exam that will be performed before th etreatment and 2 or 3 weeks after treatment initiation). The treatment cycle corresponds to 75-225 mg of elemental iron per day.
Two sachetts daily are recommended for prevention of iron deficiency.

Prevention and mild nutritional deficiency of iron can be treated in small doses..

During pregnancy (second and third trimesters), a low dosage regimen (75 mg elemental iron, corresponding to two sachets a day) is recommended. Iron requirements during the second half of pregnancy are about 6 mg/day.

Pediatric population
POLY-IRON® should not be used in children that weigh less than 12 kg.
The usual daily dose for children is 1-2 sachetts daily (i.e. 3-6 mg elemetary Iron/kg/day), depending on age and body weight.
Maximum daily dose is 200 mg.

POLY-IRON® should not be used for the prevention of amemia in children due to the high elemental Iron content in this product.

Your doctor will advise you on how long you should use this medicine, which is usually not more than six months. Usually, administration is discontinued three months after anemia has been treated. If you need to go to another doctor or hospital, please tell them that you are using **POLY-IRON®**.

If you take more POLY-IRON® than you should

If you (or anyone else) has taken the content of too many sachetts at the same time or if you think that a child may have taken the content of a sachett, contact Casualty department of the nearest hospital or inform your doctor immediately. Overdose symptoms include:

- **Up to 24 hours:** stomach and intestinal poisoning including nausea and diarrhea, cardiac disorders such as low blood pressure (hypotension) and rapid heartbeat (tachycardia), changes in metabolism such as too much acid in the body (acidosis) and high blood glucose (hyperglycemia), depression of the central nervous system ranging from fatigue to coma, there may be temporary relief of symptoms.

- **After 24 hours:** stomach and intestinal poisoning and obstruction, shock, too much acid in the body (acidosis), convulsions, coma, liver failure, jaundice (yellowing of the skin or eye white), low blood glucose, problems with blood clotting, low urine production, kidney failure, fluid in the lungs.

If you forget to take POLY-IRON®

Do not take a double dose to make up for the forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at regular time. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common (affect 1 to 10 users in 100): vomiting, constipation that in some cases causes faecal emphysema, diarrhea, stomach pain, nausea and black stools.

Very Rare (affect less than 1 user in 10.000): porphyria.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects direclty to the National Drug Organisation (284 Mesogeion Av., 15562, Cholargos Greece, Tel.: + 30 21 32040380/337, Fax: + 30 21 06549585, webpage: www.eof.gr). By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE POLY-IRON®

Keep this medicine out of reach and sight of children.

Do not use this medicine after the expiry date which is stated in the pack after "EXP". The expiry date referes to the last day of that month.

Do not store above 25°C.
You should drink the medicine immediately after dilution to water.

Medines 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 protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What POLY-IRON® contains

- Active substance is ferrous gluconate. Each sachett contains 300 mg ferrous gluconate equivalent to 37.5 mg ferrous iron.
- Other ingredients are Fructose, Sorbitol, Citric acid and Lemon flavor.

What POLY-IRON® look like and the contents of the pack

Each sachett contains powder of grayish-green color and lemon scent. The resulting solution is clear in greay-green color

POLY-IRON® is available in cartons containing sachets of polyethylene/aluminum/polyethylene sheet.
Pack sizes: 10 or 30 sachetts.
Not all pack sizes may be marketed

Marketing Authorisation Holder

TARGET PHARMA Ltd, 54 Menanrdou st., 10431 Athens Greece.
Tel..: +30 210 5224 830, Fax: +30 210 5224 838.
E-mail: info@targetpharma.gr, http://www.targetpharma.gr

Manufacturer

PHARMACEUTICAL INDUSTRY PROEL EPAMEINONDAS G. KORONIS S.A.
9 Dilou st., 12134 Peristeri, Attica, Greece Tel..: +30 210 5755 711, Fax: +30 210 5748 398

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