**21 April 2016**

## Direct Healthcare Professional Communication on Hemoton® updated approved indication.

Dear Healthcare Professional

**Summary:**


- In the context of the leaflet approval for Haemoton and based on the latest updates within the prescribing information; additional data were added to different sections within the prescribing information; those sections are:
- Indications
- Dosage & administration
- Contraindications
- Warnings & precautions
- Interactions
- Pregnancy & lactation
- Effects on ability to drive and use machines
- Side effects


The information included in this letter has been endorsed by Central Administration for Pharmaceutical Affairs (CAPA) / The Egyptian Pharmaceutical Vigilance Centre (EPVC) in agreement with GlaxoSmithKline.

**Hemoton®`s newly approved label will be included in the product packs as soon as possible.**

**Detailed information that will be included in the product label:**

**Indications:**
For treatment of vitamins and minerals in multiple deficiencies including iron deficiency anemia resulting from:
- Unbalanced diet
- Old age
- Infections
- Convalescence
- Adolescence

*Haemoton may be used during pregnancy in high risk folate deficiency under close medical supervision.



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**Dosage and administration:**

**Children**

Not to be used in children.

**Elderly**

There are no relevant data available.

**Hepatic and renal impairment**

Haemoton should not to be used except under medical supervision for patients with hepatic or renal impairment.

**Contraindications:**

This medicinal product is contraindicated in:

- Hypersensitivity to any of the components
- Use in patients with inflammatory bowel disease, including regional enteritis and ulcerative colitis, intestinal strictures and diverticulae.
- Concomitant use with parenteral iron.
- Use in patients with active peptic ulcer.
- Use in patients who require repeated blood transfusion.

**Warning and precautions:**

***Vision disorders***

Cyanocobalamin (vitamin $B_{12}$) should not be used for Leber's disease or tobacco amblyopia since these optic neuropathies may degenerate further.

***Investigations***

As this product contains ferrous, stool occult blood tests may produce falsely positive results.

Ascorbic acid, a strong reducing agent, interferes with laboratory tests involving oxidation and reduction reactions. Falsely-elevated or false-negative test results may be obtained from plasma, faeces, or urine samples depending on such factors as the dose of ascorbic acid and specific method used.

***Tolerance***

Tolerance may be induced with prolonged use of large doses of vitamin C, resulting in symptoms of deficiency when intake is reduced to normal.

Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6 years of age.

**Keep this product out of reach of children.**



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-Iron preparations should be used with caution in patients with erythropoietic protoporphyria**.**

**Interactions:**

***Folic acid antagonists***

Folate deficiency states may be produced by folic acid antagonists such as methotrexate, pyrimethamine, triamterene, trimethoprim and sulphonamides.

***Oral contraceptives***

Serum concentration of vitamin $B_{6,}$ vitamin $B_{12}$ and folic acid may be decreased by use of oral contraceptives.

Large supplements of vitamin C have been reported to increase serum ethinylestradiol concentrations in women taking oral contraceptives, but a further study showed no effect on either ethinylestradiol or levonorgestrel.

***Omeprazole***

Omeprazole has been reported to impair the bioavailability of vitamin $B_{12}$ and dietary vitamin C.

***Zinc supplements***

Additionally taken zinc supplements reduce the absorption of copper and iron.

***Vitamin C***

As this medicinal product contains vitamin C, it may increase the absorption of iron in iron-deficiency states.

***Alcohol***

Alcohol may produce folate deficiency states.

***Other***

Absorption of vitamin $B_{12}$ from the gastrointestinal tract may be reduced by aminosalicylic acid, histamine $H_2$-antagonists, and colchicine.

Concomitant administration of gastric acid neutralising agents, drugs containing: bicarbonates, carbonates or oxalates, may reduce iron absorption. Oral iron preparations should not therefore be taken within 1 hour before or 2 hours after taking the above medications.

-The absorption of both iron salts and tetracyclines is diminished when taken together orally. If treatment with both drugs is required, a time interval of about 2 to 3 hours should be allowed between them. A suitable interval is also advised if an iron supplement is needed in patients given trientine. Iron is chelated by acetohydroxamic acid, reducing the absorption of both.

-Absorption of iron may be reduced in the presence of antacids and proton pump inhibitors which reduce stomach acid. Iron absorption may also be reduced in the presence of food (e.g. tea, coffee, wholegrain cereals, eggs and milk), neomycin and cholestyramine. Bicarbonates, carbonates, oxalates,



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or phosphates, may impair the absorption of iron by the formation of insoluble complexes. Iron absorption may be increased by ascorbic or citric acid.

-Iron absorption may be reduced with calcium, oral magnesium salts and other mineral supplements, zinc and trientine. If treatment with both iron and trientine is necessary a suitable interval is advised.

-The response to iron may be delayed in patients receiving systemic chloramphenicol. Chloramphenicol delays plasma clearance of iron and incorporation of iron into red blood cells by interfering with erythropoiesis.

-The hypotensive effect of methyldopa is reduced by iron.

-Concomitant use of iron and dimercaprol should be avoided as toxic complexes may form.

-Iron reduces the absorption of fluoroquinolones, levodopa, carbidopa, entacapone, bisphosphonates, penicillamine, thyroid hormones such as levothyroxine (give at least 2 hours apart), mycophenolate, cefdinir and zinc. Iron possibly reduces the absorption of eltrombopag (give at least 4 hours apart).

-Serum levels of anticonvulsant drugs may be reduced by the co-administration of folate e.g. folic acid possibly reduces the plasma concentration of phenobarbital, phenytoin and primidone.

-Concomitant use of folic acid with raltitrexed should be avoided.

-Absorption of folic acid is possibly reduced by sulfasalazine

**Pregnancy and lactation:**

Haemoton may be used during pregnancy in high risk folate deficiency under close medical supervision.

**Effects on ability to drive and use machines:**

Haemoton does not affect the ability to drive and use machines

**Side effects:**

Side effects may include nausea, vomiting, diarrhoea, constipation and other gastro-intestinal disturbances. Side effects may be minimized by taking the product with or after food or by starting with a small dose and increasing gradually.

Haemosiderosis may occur as a result of excessive or mistaken therapy.

Rarely, folic acid may cause allergic reactions and gastrointestinal disturbances.



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Ascorbic acid is usually well tolerated.

Copper salts can produce severe GIT disturbance and hepatotoxicity.

Vitamin B 12: Allergic hypersensitivity reactions have occurred. Other adverse events include gastrointestinal disturbance, fever, chillis, hot flushing, dizziness, malaise.

**Enclosed the updated insert leaflet for Haemoton which is approved by MOH**

**Further information on recommendations to healthcare professionals:**

Please share the information in this letter with relevant colleagues and health care personnel.



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