SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Phyllosan Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
-Ferrous fumarate 35.0mg/tablet
-Nicotinic acid 8.5mg/tablet
-Thiamine mononitrate 0.166mg/tablet
-Riboflavine 0.333mg/tablet
-Ascorbic acid 5.0mg/tablet

3 PHARMACEUTICAL FORM
Tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
Prophylaxis of deficiency states of iron, B vitamins and vitamin C

4.2 Posology and method of administration
Route of administration: oral
Adults and children aged 12 years and over
Two tablets three times daily, after meals
Not to be given to children under 12 years of age except on medical advice
4.3 Contraindications
The product is contra-indicated for anaemias, other than iron deficiency anaemia and known hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use
The label will state

Important warning: contains iron. Keep out of the reach and sight of children, as overdose may be fatal. This will appear on the front of the pack within a rectangle in which there is no other information.

Keep out of the reach of children
If symptoms persist, consult your doctor

4.5 Interaction with other medicinal products and other forms of interaction
Absorption of iron may be decreased by tetracyclines (and vice versa), and antacids.

4.6 Pregnancy and lactation

The product is not contraindicated during pregnancy and lactation. However, as with all medicines during this period, caution should be exercised.

4.7 Effects on ability to drive and use machines
None known
4.8 Undesirable effects
Oral doses of iron preparations rarely produce gastro-intestinal irritation with nausea and vomiting. Occasionally, continued administration may cause constipation, particularly in the elderly.

4.9 Overdose
Symptoms
Initial symptoms of iron overdose include nausea, vomiting, diarrhoea, abdominal pain, haematemesis, rectal bleeding, lethargy and circulatory collapse. Hyperglycaemia and metabolic acidosis may occur in severe cases. After a latent phase, relapse may occur, manifested by hypotensions, coma and liver necrosis and renal failure.

Treatment
In children: Administer an emetic (syrup of ipecac) followed by gastric lavage with desferrioxamine solution (2g/l) followed by instillation of desferrioxamine 5g in 50-100ml water into the stomach. In severe poisoning 15mg/kg of desferrioxamine should be given by slow intravenous infusion to a maximum 80mg/kg/24 hours, together with supportive measures. In less severe poisoning, intramuscular desferrioxamine 1g, 4 - 6 hourly is recommended. Serum iron levels should be monitored throughout.

In adults: Administer an emetic. Gastric lavage with desferrioxamine solution (2g/l) may be necessary, followed by desferrioxamine 5g in 50-100ml water instilled into the stomach. A drink of mannitol or sorbitol should be given to induce bowel emptying. In severe poisoning 15mg/kg of desferrioxamine should be given by slow intravenous infusion to a maximum of 80mg/kg/24 hours. In less severe poisoning, intramuscular injection of desferrioxamine 50mg/kg up to maximum dose of 4g should be given. Serum iron levels should be monitored throughout.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Ferrous fumarate: provides an easily absorbable source of iron.
<table>
<thead>
<tr>
<th>Thiamine mononitrate</th>
<th>Provides essential B + C vitamins</th>
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<tbody>
<tr>
<td>Nicotinic acid</td>
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</tr>
<tr>
<td>Ascorbic acid</td>
<td>Provides essential B + C vitamins</td>
</tr>
<tr>
<td>Riboflavins</td>
<td>Provides essential B + C vitamins</td>
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5.2 **Pharmacokinetic properties**

B + C vitamins Are well absorbed from the gastrointestinal tract and are widely distributed in the body tissues. That in excess of the body’s requirements is excreted in the urine.

Ferrous fumarate is irregularly and incompletely absorbed from the gastrointestinal tract and eliminated in the faeces. Absorption increases in conditions of iron deficiency.

5.3 **Preclinical safety data**

Not applicable

6 **PHARMACEUTICAL PARTICULARS**

6.1 **List of excipients**

Calcium phosphate, icing sugar, starch, powdered acacia, talc, magnesium stearate, sucrose, calcium carbonate, gum sandarac substitute, special wax WG 10765, titanium dioxide (E171), opalux black dye AS 8110 (E153)

6.2 **Incompatibilities**

None known
6.3 Shelf life
3 years — blister strips/HDPE bottle with polypropylene screw cap
2 years — HDPE bottle with child resistant tamper evident closure

6.4 Special precautions for storage
Store below 25ºC

6.5 Nature and contents of container

a 250µ opaque PVC blister strips with a 20µ aluminium foil backing containing 30 tablets per strip. The strips are contained in a boxboard carton of 60 or 150 tablets

b cylindrical white polyethylene (HDPE) bottle with a laminate membrane neck seal, a polypropylene screw cap and polyether wad containing 90 or 150 tablets

c cylindrical white polyethylene (HDPE) bottle with a red polyethylene child resistant tamper evident lined closure. The bottle is fitted with a polyether wad containing 90 tablets

6.6 Special precautions for disposal
None stated

7 MARKETING AUTHORISATION HOLDER

Ayrton Saunders Ltd
9 Arkwright Road
8 MARKETING AUTHORISATION NUMBER(S)
PL 16431/0058

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
24th November 1994 / 23rd November 1999

10 DATE OF REVISION OF THE TEXT
05/03/2011