

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Givitol Capsules

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

##### Active Substances

Ferrous Fumarate (equivalent to 100mg of elemental iron)	305.00	mg
Sodium Ascorbate	56.0	mg
Nicotinamide	10.0	mg
Thiamine Mononitrate	2.0	mg
Riboflavin	2.0	mg
Pyridoxine Hydrochloride	4.0	mg
Folic Acid	0.50	mg

For excipients, see section 6.1.

#### 3 PHARMACEUTICAL FORM

Capsule, hard

Size No. 2, opaque, hard gelatin capsules having a maroon body, and scarlet cap, imprinted with the name 'Givitol' on both sections, and containing a brown and yellow coloured powder.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

Givitol is indicated for the prophylaxis of iron and folic acid deficiencies after the first 13 weeks of pregnancy. Givitol is indicated particularly when inadequate diet calls for supplementary vitamins B and C.

##### 4.2 Posology and method of administration

For oral administration.

For prophylaxis: 1 capsule daily.

##### 4.3 Contraindications

Contraindicated in patients with megaloblastic anaemia due to vitamin B<sub>12</sub> deficiency and in patients with a known hypersensitivity to the product or its ingredients. Givitol is also contraindicated in patients with haemochromatosis and iron overload syndrome.

##### 4.4 Special warnings and precautions for use

Givitol is intended only for the prevention of iron and folic acid deficiencies in pregnancy; the dose of folic acid provided is inadequate for the treatment of megaloblastic anaemias.

The development of anaemia despite prophylaxis with Givitol requires further investigation and appropriate therapy.

Use with caution in patients with haemoglobinopathies and haemolytic anaemias.

Caution is advised in individuals with a family history of haemochromatosis or iron overload syndromes as these conditions may be under diagnosed and overdose may be fatal.

There have been no reports of dependence or tolerance to Givitol capsules.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

Iron chelates with concomitantly administered tetracyclines, and absorption of both agents may be impaired. Absorption of iron may be reduced in the presence of antacids. Absorption of levodopa may be reduced by iron, and its effect antagonised by pyridoxine.

#### **4.6 Pregnancy and lactation**

Givitol is indicated for the prophylaxis of iron and folic acid deficiencies, after the first 13 weeks of pregnancy. It should only be taken during the first 13 weeks of pregnancy in consultation with a doctor. However, administration of drugs during the first trimester of pregnancy requires careful assessment of potential risks versus benefits to be gained.

#### **4.7 Effects on ability to drive and use machines**

Does not affect ability to drive and use machines.

#### **4.8 Undesirable effects**

Side effects may include nausea, diarrhoea, constipation and other gastro-intestinal disturbances.

#### **4.9 Overdose**

Symptoms of iron poisoning are nausea, vomiting, abdominal pain, diarrhoea, haematemesis, and rectal bleeding. Hypotension, coma and hepatocellular necrosis occur later. Mortality is reduced with intensive and specific therapy with desferrioxamine, which chelates iron. The stomach should be emptied at once, preferably by inducing vomiting as this is quickest. Gastric lavage in hospital should follow as soon as possible, leaving a solution of 5-10g of desferrioxamine mesylate in 50-100ml of water in the stomach. The serum iron concentration is measured and parenteral desferrioxamine given to chelate absorbed iron in excess of expected iron binding capacity.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic Group: Iron, multivitamins and folic acid;  
ATC code: B03AE02.

Givitol is indicated for the prophylaxis of iron and folic acid deficiencies in pregnancy, particularly when inadequate diet calls for supplementary vitamins B and C.

A daily dose of 100mg iron and 200-500 micrograms of folic acid is recommended for the prevention of iron and folic acid deficiencies during pregnancy. Givitol contains 305.00mg ferrous fumarate, equivalent to 100mg of elemental iron, and 500 micrograms of folic acid, and thus one capsule daily provides a suitable prophylactic dose.

Supplements of sodium ascorbate, riboflavin, thiamine mononitrate, nicotinamide and pyridoxine hydrochloride are useful when inadequate diet may cause reduced intake of vitamins B and C.

## 5.2 Pharmacokinetic properties

Folic acid is rapidly absorbed, mainly from the proximal part of the small intestine. Iron is irregularly and incompletely absorbed from the gastro-intestinal tract, the main sites of absorption being the duodenum and jejunum. Absorption is aided by the acid secretion of the stomach or by dietary acids, and is more readily affected when the iron is in the ferrous state. Absorption is also increased in conditions of iron deficiency or in the fasting state, but is decreased if body stores are overloaded.

## 5.3 Preclinical safety data

Not applicable.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Lactose

Capsule Shell Constituents:

Erythrosine (E127)

Indigotine (E132)

Titanium Dioxide (E171)

Gelatin

## 6.2 Incompatibilities

Not applicable.

## 6.3 Shelf Life

Two years.

## 6.4 Special precautions for storage

Store below 25°C.

## 6.5 Nature and contents of container

Cylindrical polypropylene containers with polyethylene snap-close caps.

Pack size: 28, 30, 100 and 250 capsules.

High density polyethylene (HDPE) bottle with a child resistant screw cap composed of a HDPE outer, polypropylene inner and an expanded polyethylene (EPE) liner.

Pack size: 28 and 30 capsules.

Aluminium strip foils (7 x 4) packed into a cardboard carton.

Pack size: 28 capsules.

Not all pack sizes may be marketed.

**6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

No special requirements.

**7 MARKETING AUTHORISATION HOLDER**

Galen Limited  
Seagoe Industrial Estate  
Craigavon  
BT63 5UA  
United Kingdom

**8 MARKETING AUTHORISATION NUMBER**

PA 185/7/1

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 22 April 1980

Date of last renewal: 22 April 2005

**10 DATE OF REVISION OF THE TEXT**

January 2006