

## PART II

## SUMMARY OF PRODUCT CHARACTERISTICS

## 1. TRADE NAME OF THE MEDICINAL PRODUCT

Multivite Plus Tablets

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Calcium Carbonate Ph. Eur.	250 mg
Ascorbic acid (as Sodium Ascorbate) Ph. Eur.	100mg
Folic Acid Ph. Eur.	2.5mg
Ferrous Fumerate Ph. Eur.	150mg
Vitamin D2	400IU
Vitamin A acetate	2250 IU

## 3. PHARMACEUTICAL FORM

Smooth, oblong, pink, film-coated tablets.

## 4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Vitamin and mineral supplementation.

4.2 Posology and Method of Administration

For oral administration only.

(a) Adults

1 tablet daily, or as directed by a physician.

(i) Elderly

Not applicable.

(ii) Children

Not applicable.

#### 4.2 Posology and Method of Administration (Cont/d)

(iii) Infants and Neonates

Not applicable.

(iv) Special Groups

Not applicable.

#### 4.3 Contraindications

Multivite plus is contraindicated in pernicious anaemia.

Use in patients with a known hypersensitivity to any of the active constituents.

Use in patients with paroxysmal nocturnal haemoglobinuria, haemosiderosis, haemochromatosis, active peptic ulcer, repeated blood transfusion, regional enteritis and ulcerative colitis.

#### 4.4 Special Warnings and Special Precautions for Use

Side effects including nausea and vomiting, gastrointestinal discomfort, diarrhoea, constipation, anorexia and darkening of stools may occur.

Prolonged excessive ingestion of vitamins A and D can lead to hypervitaminosis states which may also occur if foods high in these vitamins, (for example liver), are ingested in association with the recommended doses of this product.

Due allowance should always be made of intake of these vitamins from other sources.

Some post-gastrectomy patients show poor absorption of iron.

Care is needed when treating iron-deficiency anaemia in patients with treated or controlled peptic ulceration.

Since anaemia due to combined iron and vitamin B12 or folate deficiencies may be microcytic in type, patients with microcytic anaemia resistant to therapy with iron alone should be screened for vitamin B12 or folate deficiency

Caution should be exercised when administering folic acid to patients who may have folate dependent tumours.

Multivite Plus tablets must be kept out of the reach of children.

Rarely, allergic reactions may occur.

#### 4.5 Interactions with other Medications and other forms of Interactions

The absorption of iron salts is decreased in the presence of antacids.

Care should be taken with the concomitant use of this preparation with tetracyclines as iron salts diminish the absorption of tetracyclines.

Iron reduces the absorption of penicillamine.

Chloramphenicol delays plasma iron clearance, incorporation of iron into red blood cells and interferes with erythropoiesis.

Some inhibition of iron absorption may occur if it is taken with cholestyramine, tea, eggs or milk.

Co-trimoxazole, chloramphenicol or sulphasalazine may interfere with folate metabolism.

Plasma levels of phenytoin, phenobarbitone and primidone may be lowered when co-prescribed with folic acid.

#### 4.6 Pregnancy and Lactation

Large doses of vitamin A have been found to be teratogenic if administered during the first trimester of pregnancy. Vitamin D given during the last trimester of pregnancy may cause hypercalcaemia in infants.

It is advised that if possible women receiving Vitamin D do not breast feed their infants as this may lead to the development of hypercalcaemia in the infant.

#### 4.7 Effects on ability to Drive and Use Machines

Not applicable.

#### 4.8 Undesirable Adverse Effects

None reported.

#### 4.9 Overdose

Symptoms of overage with iron salts include epigastric pain, nausea and vomiting, haematemesis and circulatory collapse. In severe cases, encephalopathy, acute hepatic necrosis and acute renal failure may develop after a latent period.

#### 4.9 Overdose (Cont/d)

Vomiting should be induced immediately followed as soon as possible by parenteral injection of desferrioxamine mesylate and then gastric lavage.

In the meantime it is helpful to give milk and /or 5% sodium bicarbonate solution by mouth. If desferrioxamine is not available, leave 300ml of 1% to 5% sodium bicarbonate the stomach. Fluid replacement is essential, recovery may be complicated by long term sequelae such as hepatic necrosis, pyloric tenosis or acute toxic encephalitis which may lead to CNS damage.

### 5. PHARMACOLOGICAL PROPERTIES

#### 5.1 Pharmacodynamic Properties

Pharmacodynamic properties and pharmacokinetics of the active ingredient.

Vitamin and mineral supplement.

#### 5.2 Pharmacokinetic Properties

None known.

#### 5.3 Preclinical Safety Data

### 6. PHARMACEUTICAL PARTICULARS

#### 6.1 List of Excipients

Povidone K26-28  
Magnesium Stearate  
Maize Starch

Film Coating:

Hypromellose  
Ethyl Cellulose  
Acetylated monoglycerides  
Polysorbate 80  
Propylene Glycol  
Opaspray K-1-1318 containing:

Titanium dioxide (E171), Hydroxypropyl cellulose, Sunset yellow FCF (E110), Erythrosine (E127)

6. **PHARMACEUTICAL PARTICULARS (Cont/d)**

6.2 **Incompatibilities**

None known

6.3 **Shelf Life**

(a) Product in unopened state

2 years when stored below 25°C

(b) Product after opening where this may be different.

Not relevant.

(c) Reconstituted product where appropriate

Not relevant.

6.4 **Special Precautions for Storage**

Store below 25°C

6.5 **Nature and Contents of Containers**

Polypropylene securitainer type containers, fitted with tamper evident polyethylene lid.

Pack size: 30 and 100 tablets

6.6 **Instructions for Use/Handling**

No special instructions.

**7. NAME AND ADDRESS OF MARKETING AUTHORISATION HOLDER**

Goldshield group Plc  
trading as Goldshield Pharmaceuticals  
NLA Tower  
Croydon CR0 OXT  
United Kingdom

**8. MARKETING AUTHORISATION NUMBER**

PA 701/5/1

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

1 April 1983 / 1 April 1998

**10. DATE OF (PARTIAL) REVISION OF THE TEXT**