### **One-Up Gold D**

### 1. Generic Name

Multivitamin, Multimineral, L-Glutamic Acid And DL-Methionine Tablets

## 2. Qualitative and quantitative Composition:

Each film coated tablet contains:	
Heavy Magnesium Oxide I.P.	. 30 mg
Vitamin C I.P.	. 100 mg
Niacinamide I.P	50 mg
Zinc Oxide I.P. eq. to Elemental Zinc	22.5 mg
Vitamin E Acetate I.P	25 IU
Calcium Pantothenate I.P.	12.5 mg
Vitamin A Concentrate Powder I.P	5000 IU
Cupric Oxide Eq. to Elemental Copper	2.5 mg
Manganese Sulfate U.S.P. Eq.to Elemental Manganese	2.5 mg
Thiamine Mononitrate I.P	10 mg
Riboflavin I.P	10 mg
Pyridoxine Hydrochloride I.P	3 mg
Folic Acid I.P	1500 mcg
Chromium Picolinate I.P. Eq. to Elemental Chromium	100 mcg
Biotin I.P	60 mcg
Selenious Acid I.P. Eq. to Elemental Selenium	60 mcg
Vitamin D <sub>3</sub> I.P	400 IU
Methylcobalamin I.P	500 mcg
L- Glutamic Acid U.S.P	100 mg
DL- Methionine B.P	25 mg
Colour: Caramel U.S.PNF	

Appropriate overages of vitamin added to compensate for loss on storage.

The excipients used are Dibasic Calcium Phosphate, Microcrystalline Cellulose, Polyvinyl Pyrrolidone, Isopropyl Alcohol, Mannitol, Ethyl Cellulose, Methylene Chloride, Polyplasdone XL-10, Colloidal Silicon Dioxide, Magnesium Stearate, Hydroxypropyl Methyl Cellulose, Polyethylene Glycol 6000, Talcum, Beeswax, Carnauba Wax.

# 3. Dosage form and strength

**Dosage form:** Film coated tablet

Strength: 1 mg

# 4. Clinical particulars

#### 4.1 Therapeutic indication

It is indicated for the Vitamins and Minerals deficiency states in adult patients.

# 4.2 Posology and method of administration

Posology

Dosage And Administration:

The recommended dose of One-up Gold D is one tablet daily preferably taken one hour after meals or as suggested by the physician. The tablet should be swallowed whole with water. One-up Gold D tablets may be administered during pregnancy and lactation at the recommendation of the physician.

Method of administration

Tablet should be taken orally

### **4.3 Contraindications**

Know hypersensitivity to any content in this product

Pre-existing hypervitaminosis

Hypercalcaemia,

Haemochromatosis and other iron storage disorders.

Unsuitable for babies

### 4.4 Special warnings and precautions for use

Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6 years. Keep this product out of reach of children. In case of accidental overdose, consult a doctor immediately. Whilst taking tablets, both protein and energy are also required to provide complete nutrition in the daily diet. No other vitamins, minerals or supplements with or without vitamin A should be taken with this preparation except under medical supervision. Taking this product may result in a harmless dark yellow coloration of the urine indicating that the body is using Vitamin B2 effectively. An increase in daily fluid intake will bring the urine back to normal colour. Long-term intake of high levels of vitamin A (excluding that sourced from beta-carotene) may increase the risk of osteoporosis in postmenopausal women. Evidence from Randomised Control Trials suggests that high doses (20-30 mg/day) b-carotene intake may increase the risk of lung cancer in current smokers and those previously exposed to asbestos. This high-risk population should consider the potential risks and benefits of One-up Gold D, which contain 4.5mg per recommended daily dose, before use. Nausea, upset stomachs, or unpleasant taste may occur. If any of these effects persist or worsen, notify the physician.

### **4.5 Drugs interactions**

Folic acid can reduce the plasma concentration of phenytoin. Oral iron and zinc sulphate reduce the absorption of tetracyclines.

# 4.6 Use in special populations (Pregnancy, Lactation and Breast Feeding)

No data is available

# 4.7 Effects on ability to drive and use machines

No data is available regarding the effects on the ability to drive and use machines.

#### 4.8 Undesirable effects

No data available

#### **Reporting of adverse reactions**

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 directly via any point of contact of Torrent Pharma available at:

<u>https://www.torrentpharma.com/index.php/site/info/adverse\_event\_reporting</u> By reporting side effects, you can help provide more information on the safety of this medicine.

### 4.9 Overdose

Treatment is directed to minimise or prevent further absorption of the medication, i.e. by inducing emesis, gastric lavage, administering desferrioxamine solution (2 g/l), mannitol /sorbitol drink to induce small bowel emptying. For Severe poisoning - in the presence of shock and/or coma with high serum iron levels (>142  $\mu$ mol/l) immediate supportive measures plus i.v. infusion of desferrioxamine should be instituted. The recommended dose of desferrioxamine is 5 mg/kg/h by slow i.v. infusion up to a maximum of 80 mg/kg/24 hours. Warning: hypotension may occur if the infusion rate is too rapid. For Less severe poisoning-i.m. desferrioxamine 50 mg/kg up to a maximum dose of 4 g should be given. Serum iron levels should be monitored throughout, and any fluid or electrolyte imbalance should be corrected.

### **5** Pharmacological properties

### 5.1 Pharmacodynamic properties

No data available

### 5.2 Pharmacokinetic properties

No data available

### **6** Nonclinical properties

### 6.1. Animal Toxicology or Pharmacology

No data on animal studies of safety pharmacology are available.

#### 7 Description

Multivitamin, Multimineral, L-Glutamic Acid And DL-Methionine Tablets are Dark brown coloured, elongated, biconvex, both sides plain & film coated tablets.

The excipients used are Dibasic Calcium Phosphate, Microcrystalline Cellulose, Polyvinyl Pyrrolidone, Isopropyl Alcohol, Mannitol, Ethyl Cellulose, Methylene Chloride, Polyplasdone XL-10, Colloidal Silicon Dioxide, Magnesium Stearate, Hydroxypropyl Methyl Cellulose, Polyethylene Glycol 6000, Talcum, Beeswax, Carnauba Wax.

#### **8** Pharmaceutical particulars

#### **8.1 Incompatibilities**

Not applicable

#### 8.2 Shelf-life

Do not use later than date of expiry.

#### 8.3 Packaging information

One-Up Gold D is available in a blister Pack of 10 Tablets.

#### 8.4 Storage and handing instructions

Store below 25°C, Protected from Light and Moisture.

Keep out of reach of children.

# **9** Patient Counselling Information

Ask the patients to inform the treating physicians in case of any of the below:

- Have any allergies
- Have kidney or liver problems
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have any serious illness
- Are taking any medicines (prescription, over the counter, vitamins, or herbal products)

# **10 Details of manufacturers**

Akums Drugs & Pharmaceuticals Ltd.

Plot No. 19,20 & 21

Sector-6A, I.I.E., SIDCUL, Ranipur,

Haridwar-249 403 (Uttarakhand)

# 11 Details of permission or licence number with date

Mfg. Lic. No. 5/UA/SC/P-2004 Issued on 11.01.2023

### 12. Date of revision

Dec 2024

### **MARKETED BY**

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# IN/ One-Up Gold D 1 mg/Dec-2024/02/PI