

**1. NAME OF THE MEDICINAL PRODUCT**

RIBOSAM TABLET 3MG

**2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS**

Each tablet contains:

Riboflavin (Vitamin B2)

B.P.3mg

Excipients.....q.s.

{For a full list of excipients, see section 6.1}

**3. PHARMACEUTICAL FORM**

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Orange colored plain round tablets for oral use

## 4. Clinical particulars

### 4.1 Therapeutic indications

- Riboflavin deficiency (aribo flavinosis- Manifestations of which include glossitis, stomatitis, cheilosis, the heart manifestations of beriberi, the skin manifestations of pellagra, corneal vascularisation and polyneuritis).

Possibly effective also for the following conditions:

- High levels of homocysteine in the blood (hyperhomocysteinemia). Taking riboflavin by mouth for 12 weeks decreases levels of homocysteine by up to 40% in some people with a specific gene type.
- Migraine. Taking high-dose riboflavin by mouth seems to modestly reduce the severity of migraine headaches in adults. It is unclear if it helps in children.
- Helps in the Prevention of Cataract.

### 4.2 Posology and method of administration

#### Posology

The following doses have been studied in scientific research.

By Mouth:

- For treating low levels of riboflavin (riboflavin deficiency) in adults: 5-30mg of riboflavin (Vitamin B2) daily in divided doses.
- For preventing Migraine headaches: 400mg of riboflavin per day. It may take up to three months to get the best results.
- For preventing cataracts: A daily dietary intake of approximately 2.6mg of riboflavin has been used. A combination of 3mg of riboflavin plus 40mg Niacin daily has been used.
- The daily recommended dietary allowances (RDAs) of riboflavin are:  
Adult Males 1.3mg daily.  
Adult Females 1.1mg daily.  
During pregnancy, the RDA is 1.4mg and during breastfeeding RDA is 1.6mg.  
Recommended amounts for children depend on age.  
However Not recommended for children under 3years of age.

### 4.3 Contraindications

Hypersensitivity to the active substance or any of the excipients.

#### 4.4 Special warnings and precautions for use

**Pregnancy and Breast-feeding:** Riboflavin is likely safe for pregnant or breast-feeding women when taken in the amounts recommended. The recommended amounts are 1.4mg per day for pregnant women and 1.6mg per day in breast-feeding women.

Riboflavin is possibly safe when taken by mouth in larger doses, short-term. Some research shows that riboflavin is safe when taken at a dose of 15mg once every 2 weeks for 10 weeks.

Riboflavin absorption is decreased in people with these conditions: Hepatitis, Cirrhosis, and Biliary.

Keep out of reach of children.

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

**Antibiotics** (Tetracycline antibiotics) Interaction rating: Moderate.

Riboflavin might decrease the amount of tetracycline that the body can absorb. Taking riboflavin along with tetracyclines might decrease the effectiveness of tetracyclines.

To avoid this interaction, take riboflavin 2 hours before or 4 hours after taking tetracyclines.

**Anticholinergic drugs:** Interaction rating: Minor.

Taking these anticholinergics with riboflavin (Vitamin B2) can increase the amount of riboflavin that is absorbed in the body. But it is not known if this interaction is important.

**Tricyclic Antidepressants:** Interaction rating: Minor.

Some medications for depression can decrease the amount of riboflavin in the body.

This interaction is not a big concern because it only occurs with very large amounts of some medications for depression.

**Phenobarbital:** Interaction rating: Minor.

Riboflavin is broken down by the body. Phenobarbital might increase how quickly riboflavin is broken down in the body. It is not clear if this interaction is significant.

**Probenecid:** Interaction rating: Minor.

Probenecid can increase how much riboflavin is in the body. This might cause there be too much riboflavin in the body. It is not known if this interaction is a big concern.

#### 4.6 Effects on ability to drive and use machines

Riboflavin has no influence on the ability to drive and use machines.

#### **4.7 Undesirable effects**

Riboflavin is safe for most people when used orally. In some people however, Riboflavin can cause the urine to turn yellow-orange colour. When taken in high doses, riboflavin might cause diarrhea, and an increase in urine output.

#### **4.8 Overdose**

Overdose is not to be expected within the stated dosage range.

No case of overdose has been reported.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamics properties**

Riboflavin is a vitamin (B2). It is water-soluble and co-enzyme essential for the metabolism of protein, carbohydrate or fatty acid.

#### **Mechanism of Action**

Riboflavin is a component of flavoprotein enzymes that are necessary for normal tissue respiration; plays a role in activation of Pyridoxine and conversion of tryptophan to Niacin.

#### **5.2 Pharmacokinetic properties**

Riboflavin is absorbed from the GI Tract and in the circulation is bound to plasma proteins.

Although widely distributed, little is stored in the body and amounts in excess of requirements are excreted in the urine.

Metabolism of riboflavin takes place in the Liver.

### **5.3 Preclinical safety data**

Not applicable.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Di-calcium phosphate

Maize starch

Purified Talc

Magnesium stearate

Gelatin

Methyl-paraben

Propyl-paraben

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

24 months from the date of manufacturing.

#### **6.4 Special precautions for storage**

Protect from heat and light and store in a cool dry place below 30°C

#### **6.5 Nature and contents of container**

Bulk pack tablet whose quality has been approved by quality control department in polythene bags in 1000's by weight. Seal the bags and place them in previously cleaned 350cc plastic secure-containers.

#### **6.6 Special precautions for disposal**

No special requirements.

Any unused product or waste material should be disposed of in accordance with local requirements.

### **7. Marketing Authorization Holder**

**SAM PHARMACEUTICAL LIMITED**

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**8. Marketing Authorization number:**

**04-0467**

**9. Authorization/ Renewal of the Authorization**

**Renewal date: 01<sup>st</sup> June 2021**

**10. Date of Revision of the Text**

**17<sup>th</sup> August 2025.**