

## **MODULE 1: ADMINISTRATIVE AND PRODUCT INFORMATION OF ORHEPTAL CAPSULES**

### **1.3 PRODUCT INFORMATION:**

#### **1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)**

##### **1. Name of the medicinal product: ORHEPTAL CAPSULES**

##### **2. Qualitative and Quantitative Composition**

###### **Composition:**

###### **Each hard gelatin capsule contains:**

Ferrous Fumarate BP ...  
Equivalent to elemental iron .....30 mg  
Copper sulphate USP.....  
Equivalent to elemental Copper .....1 mg  
Zinc sulphate Monohydrate USP  
Eqvt. To elemental Zinc .....15 mg  
Manganese Sulphate USP  
Eqvt. To elemental Manganese ...3 mg  
Calcium Carbonate. BP  
Eqvt. To elemental Calcium .....90 mg  
Magnesium Hydroxide BP  
Eqvt to elemental Magnesium .....45 mg  
Thiamine Nitrate BP .....5 mg  
(Vitamin B1)  
Cyanocobalamin (coated)  
Eqvt. To Vitamin B 12 BP .....1 mcg  
Folic acid BP .....100 mcg

##### **3. Pharmaceutical Form**

Maroon/Maroon coloured hard gelatin size “0” capsules with monogram “Orheptal” printed in white on cap and “Orheptal” printed in yellow on body.

##### **4. Clinical Particulars**

###### **4.1 Therapeutic indications**

Orheptal provides haematopoeitic action of the Vitamin B12, Iron, Manganese and Copper salts. Orheptal simultaneously supplies the added advantage of factors that stimulate the appetite and have a general roborant effect. Orheptal is an ideal preparation in debility following loss of blood, operations, childbirth, abortion, accidents and in convalescence.

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## **4.2 Posology and method of administration**

**Route of Administration:** Oral

**Conditions of Administration:**

The Standard dosage is 1 capsule 2 times daily for adults and 1 capsule daily for children and adolescents, preferably before meals. Orheptal may be taken a quarter of an hour before meals for rapid response. Standard dosage may be increased at the discretion of the Physician in cases of deficiency. Orheptal should be stored in a cool & dry place.

### **4.3 Contraindications**

Tetracyclines should not be taken within one hour of administration of the product.

### **4.4 Pregnancy and lactation**

The drug is not recommended in pregnant & breast feeding women

### **4.5 Undesirable effects**

Ingredients present in Orheptal Capsules are generally well tolerated. But mild side effects are reported like: Nausea, headache, constipation, flatulence with ingredients present in the Orheptal.

### **4.6 Special warning and precautions for use**

None

### **4.7 Interaction with other medicinal products and other forms of interactions**

None

### **4.8 Effects on ability to drive and use machine**

None

### **4.9 Overdose**

Discontinue use. Seek immediate medical advice

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## 5. Pharmacological Properties

### 5.1 Pharmacodynamics Properties

#### Pharmacotherapeutic group:

#### Calcium carbonate:

Calcium carbonate acts by directly increasing calcium stores within the body. Calcium carbonate is a basic inorganic salt that acts by neutralizing hydrochloric acid in gastric secretions. It also inhibits the action of pepsin by increasing the pH and via adsorption.

**Vitamin B12** - Vitamin B12 is necessary for normal hematopoiesis (promotes maturation of erythrocytes). It has a beneficial effect on liver function and the nervous system. It also activates the coagulation of blood in high doses and causes an increase in the activity of thromboplastin and prothrombin.

#### Zinc

Zinc acts as a cofactor for more than 70 different enzymes. Zinc dependent enzymes are involved in the metabolism of carbohydrates, lipids, and proteins. Zinc facilitates wound healing, normal growth rates, normal skin hydration and maintains senses of taste and smell. It provides normal growth and tissue repair. It also helps in development of cell mediated immunity

#### Mechanism of Action of Vitamin B-Complex

Vitamin B-complex are group of vitamins, which include Thiamine (B1), Riboflavin (B2), Niacin(B3), Pantothenic acid (B5), Pyridoxine (B6), Cyanocobalamin (B12), Folic acid and Biotin.

These vitamins are essential for the breakdown of carbohydrates into glucose (this provides energy for the body), the breakdown of fats and proteins (which aids the normal functioning of the nervous system), muscle tone in the stomach and intestinal tract, Skin, Hair, Eyes, Mouth and Liver

### 5.2 Pharmacokinetic Properties

#### Pharmacokinetics:

#### Folic Acid

Folic acid is absorbed mainly from the proximal part of the small intestine. Folate polyglutamates are

Considered to be deconjugated to monoglutamates during absorption. Folic acid rapidly appears in the blood where it is extensively bound to plasma proteins. Some folic acid is distributed in body tissues, some is excreted as folate in the urine and some is stored in the liver as folate.

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## **Vitamin B1 (Thiamine)**

The usual diet of a population strongly affects iron bioavailability thus recommended intakes for iron depend on diet characteristics in developing countries, where average meals may be poor in iron, iron supplementation may be considered in pre pregnant woman and adolescent girls as well. Women might then enter pregnancy with adequate iron reserves.

## **Vitamin B12**

It is bound to plasma proteins and stored in the liver. Vitamin B12 is excreted in the bile and undergoes some enterohepatic recycling.

## **Copper Sulfate (Copper)**

Copper is absorbed from the gastro-intestinal tract and its major route of excretion is in the bile

## **Manganese Sulfate (Manganese)**

Manganese salts are poorly absorbed.

## **5.3 Preclinical safety Data**

Product containing simple, widely used, well documented ingredients which are subjects of current pharmacopeias so the above data is not required.

## **6. Pharmaceutical Particulars**

### **6.1 List of excipients**

Sodium Methyl paraben BP

Sodium Propyl paraben BP

Maize Starch BP (For paste)

Maize Starch (Dried)

Purified Talc BP

Magnesium Stearate BP

Maize Starch (Dried)

Sodium Lauryl Sulphate BP

Colloidal Anhydrous Silica BP

Purified Water BP

Empty Hard Gelatin Capsule

Maroon/Maroon Size '0' with

Monogram ORHEPTAL Printed on cap  
(in white) and on body (in yellow)

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MS: Meyer Specifications

USP: United State Pharmacopeia

BP: British Pharmacopoeia

## **6.2 Incompatibilities**

Not Known

## **6.3 Shelf life**

36 months

## **6.4 Special precautions for storage**

Store below 30°C, at a dry place. Protected from light.

Keep medicines out of reach of children

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

Each Carton should contain 5 strips, each containing 6 no.of ORHEPTAL CAPSULES arranged in 2 x 3 type.

## **7. Manufacturer**

MEYER ORGANICS PVT. LTD.

10 D, 2nd Phase,

Peenya Industrial Area,

Bangalore