

## PRODUCT SUMMARY

### 1. TRADE NAME OF THE MEDICINAL PRODUCT

Trientine dihydrochloride capsules 300 mg

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Trientine dihydrochloride 300 mg  
Equivalent to 200 mg base

### 3. PHARMACEUTICAL FORM

Hard capsules (capsules)  
White capsules marked in grey ink with the company logo and "Trientine 300mg".

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic Indications

For the treatment of Wilson's disease in patients intolerant of D-Penicillamine therapy.

#### 4.2 Posology and Method of Administration

For oral use  
Adults (including elderly): 1.2-2.4 grams (4-8 capsules) daily in 2 to 4 divided doses preferably 30 minutes to 1 hour before meals.  
Children: The dose is lower than for adults and depends on age and body weight. The dose should be adjusted according to clinical response. 0.6-1.5 grams have been used at initiation of therapy.

#### 4.3 Contra-Indications

None stated.

#### 4.4 Special Warnings and Precautions for Use

Trientine is not indicated as an alternative to D-Penicillamine in the treatment of rheumatoid arthritis or cystinuria.  
Penicillamine-induced systemic lupus erythematosus may not resolve on transfer to trientine. Trientine is a chelating agent which has been found to reduce serum iron levels possibly reducing its absorption. Iron supplementation may be necessary in some cases and should be administered at a different time of the day to trientine.  
There is no evidence that calcium or magnesium antacids alter the efficacy of trientine but it is good practice to separate their administration. (i.e. antacids should be taken after meals).  
There is no advantage in using trientine and penicillamine in combination.

#### 4.5 Interactions with other Medicaments and other forms of Interaction

Trientine has been found to reduce serum iron levels.

#### 4.6 Pregnancy and Lactation

The product should be used in pregnancy only after careful consideration of the benefits compared with the risks of treatment in the individual patient. Factors which need to be borne in mind include the risks associated with the disease itself, the risk of those alternative treatments which are available and the possible teratogenic effects of trientine. The pregnancy should be monitored in order to detect possible foetal abnormality and to assess maternal serum copper levels throughout the pregnancy.  
The dose of trientine used should be adjusted in order to maintain serum copper levels within the normal range.

Babies born to mothers being treated with trientine should be monitored for serum copper and ceruloplasmin levels where appropriate.

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

None stated

#### 4.8 Undesirable Effects

Nausea on initial treatment and occasionally skin rash can occur. Duodenitis and severe colitis have been reported. Very rarely anaemia.

### 4.9 Overdose

In one reported case an overdose of 30 capsules did not produce any apparent adverse effect.

### 5. PHARMACOLOGICAL PROPERTIES

#### 5.1 Pharmacodynamic Properties

Trientine dihydrochloride is a copper-chelating agent which aids the elimination of copper from the body by forming a stable soluble complex that is readily excreted from the kidney.

#### 5.2 Pharmacokinetic Properties

None stated.

#### 5.3 Preclinical Safety Data

None stated.

### 6. PHARMACEUTICAL PARTICULARS

#### 6.1 List of Excipients

Capsule content:  
Magnesium stearate  
Colloidal anhydrous silica  
Capsule shell:  
Gelatin  
Titanium dioxide (E171)  
Grey printing ink containing:  
Shellac  
Titanium dioxide (E171)  
Iron oxide black (E172)  
Iron oxide yellow (E172)  
Propylene glycol

#### 6.2 Incompatibilities

Not known.

#### 6.3 Shelf life

36 months.  
3 months after first opening.

#### 6.4 Special Precautions for Storage

Store in a refrigerator (2°C - 8°C). Do not freeze. Store in the original container and retain the silica gel sachet in the bottle in order to protect from moisture.

#### 6.5 Nature and contents of container

100 capsules in an amber glass bottle with a polypropylene cap with induction heat seal liner, also containing a sachet of dried silica gel as desiccant.

#### 6.6 Instruction for Use/Handling

None stated.

### ADMINISTRATIVE DATA

#### 7. MARKETING AUTHORISATION HOLDER

Univar BV  
Schouwburgplein 30-34  
3012 CL Rotterdam  
The Netherlands

#### 8. MARKETING AUTHORISATION NUMBER

PL 41626/0001

#### 9. DATE OF FIRST AUTHORISATION/RENEWALS OF AUTHORISATION

8 August 1985/16 April 1996.

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

### ALL CORRESPONDENCE AND ENQUIRIES TO:

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