PRODUCT SUMMARY

1. TRADE NAME OF THE MEDICINAL PRODUCT
Trientine dihydrochloride capsules 300 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Trientine dihydrochloride HSE 300 mg
Equivalent to approx 200 mg base

3. PHARMACEUTICAL FORM
Hard gelatin capsules

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
Magnesium stearate
Aerosil 200 (Colloidal Silicon Dioxide)
Gelatin

6.2 Incompatibilities
Not known.

6.3 Shelf life
36 months.
3 months of first opening.

6.4 Special Precautions for Storage
Store in a refrigerator (2-8˚C).Do not freeze Store in its original container 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
Secretary of State for Health,
Department of Health
Health Improvement and Protection Directorate HIP
Immunisation Branch
Area 504
5th Floor, Wellington House
133-155 Waterloo Road London SE1 8UG

8. MARKETING AUTHORISATION NUMBER
PL 01511/0017

9. DATE OF FIRST AUTHORISATION/RENEWALS OF AUTHORISATION
8 August 1985/16 April 1996.

10. DATE OF (PARTIAL) REVISION OF THE TEXT
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