**Indications and usage**

Waymade Trientine Hydrochloride Capsule is indicated in the treatment of patients with Wilson’s disease who are intolerant of penicillamine. Clinical experience with Waymade Trientine Hydrochloride Capsule is limited and alternate dosing regimens have not been well-characterized; all endpoints in determining an individual patient’s dose have not been well defined.

**Waymade Trientine Hydrochloride Capsule and penicillamine cannot be considered interchangeable. Trientine Hydrochloride Capsule should be used when continued treatment with penicillamine is no longer possible because of intolerable or life endangering side effects.**

Unlike penicillamine, Waymade Trientine Hydrochloride Capsule is not recommended in cystinuria or rheumatoid arthritis. The absence of a sulphydryl moiety renders it incapable of binding cystine and, therefore, of no use in cystinuria. In 15 patients with rheumatoid arthritis, Waymade Trientine Hydrochloride Capsule was reported not to be effective in improving any clinical or biochemical parameter after 12 weeks of treatment. Waymade Trientine Hydrochloride Capsule is not indicated for treatment of biliary cirrhosis.

**WHAT DOES WAYMADE TRIENTINE HYDROCHLORIDE DO?**

Waymade Trientine hydrochloride is a chelating compound for removal of excess copper from the body. Waymade Trientine hydrochloride, USP is available as 250 mg capsules for oral administration. Waymade Trientine hydrochloride capsules, USP contain stearic acid, gelatin, titanium dioxide and FD&C yellow 6 as inactive ingredients. Imprinting ink contains shellac, propylene glycol, black iron oxide and potassium hydroxide.

Waymade Trientine hydrochloride is N,N’-bis (2-aminooethyl)-1,2-ethanediamine dihydrochloride. It is a white to pale yellow crystalline hygroscopic powder. It is freely soluble in water, soluble in methanol, slightly soluble in ethanol, and insoluble in chloroform and ether. The empirical formula is C₁₈H₂₄N₄·2HCl with a molecular weight of 219.2. The structural formula is: NH(CH₂)₂NH(CH₂)₂NH(CH₂)₂NH₂·2HCl.
Adverse reactions

Clinical experience with Waymade Trientine Hydrochloride Capsule has been limited. The following adverse reactions have been reported in a clinical study in patients with Wilson’s disease who were on therapy with Waymade Trientine hydrochloride: iron deficiency, systemic lupus erythematosus. In addition, the following adverse reactions have been reported in marketed use:

- Dystonia
- Muscular Spasm
- Myasthenia Gravis

Dosage and administration

Systemic evaluation of dose and/or interval between dose has not been done. However, on limited clinical experience, the recommended initial dose of Trientine Hydrochloride Capsule is 500-750 mg/day for pediatric patients and 750 - 1,250 mg/day for adults given in divided doses two, three or four times daily. This may be increased to a maximum of 2,000 mg/day for adults or 1,500 mg/day for pediatric patients age 12 or under.

The daily dose of Trientine Hydrochloride Capsule should be increased only when the clinical response is not adequate or the concentration of free serum copper is persistently above 20 mcg/dL. Optimal long-term maintenance dosage should be determined at 6–12-month intervals (see PRECAUTIONS, Laboratory Tests).

It is important that Trientine Hydrochloride Capsule be given on an empty stomach, at least one hour before meals or two hours after meals and at least one hour apart from any other drug, food, or milk. The capsules should be swallowed whole with water and should not be opened or chewed.

How is it supplied?

WAYMADE Trientine Hydrochloride Capsules, USP 250 mg, are hard gelatin capsules with opaque orange cap imprinted with NAV and opaque white body imprinted with 101 in black ink. They are supplied as follows: NDC 68475-200-01 in bottles of 100.

STORAGE:

Dispense in a tight container and store in a refrigerator; 2 to 8° C (36 to 46° F). Keep container tightly closed.