TRIENTINE is indicated in the treatment of patients with Wilson's disease who are intolerant of penicillamine. Clinical experience with TRIENTINE 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. TRIENTINE and penicillamine are not considered interchangeable. TRIENTINE should be used when continued treatment with penicillamine is no longer possible because of intolerance or failure with side effects.

Unlike penicillamine, TRIENTINE is not recommended in cystinuria or rheumatoid arthritis. The absence of a sulfhydryl moiety renders it incapable of binding cystine and, therefore, is not a substitute for penicillamine in such patients. TRIENTINE was tested in 15 patients with rheumatoid arthritis, TRIENTINE was reported not to be effective in improving clinical signs or biochemical parameter after 12 weeks of treatment. TRIENTINE is not indicated for treatment of biliary cirrhosis.

CONTRAINDICATIONS

Hypersensitivity to this product.

WARNINGS

Patient experience with trientine hydrochloride is limited (see CLINICAL PHARMACOLOGY). In addition, the following adverse reactions have been reported after administration of trientine hydrochloride.

1. Agranulocytosis

2. Hemolytic anemia

3. Anemia of special types

5. Hypersensitivity reaction (see CLINICAL PHARMACOLOGY). In addition, the following adverse reactions have been reported after administration of trientine hydrochloride.

ADVERSE REACTIONS

Clinical experience with trientine hydrochloride is limited. The following adverse reactions have been reported after administration of trientine hydrochloride in a clinical study in patients with Wilson's disease who were on therapy with trientine hydrochloride:

1. The occurrence of intolerable or life endangering adverse reactions were reported: hepatic; epigastric pain and tenderness; thickening, fissuring and flaking of the skin; hypochromic microcytic anemia; acute gastrosis; aphiides ulcers; abdominal pain; melena; anorexia; malaise; cramps, vomiting; periodontal disease; weakness; rhabdomyolysis. A causal relationship of these reactions to drug therapy could not be established.

2. Store protected from moisture at a temperature not exceeding 2°C to 8°C (Cold Storage).

Pack size: is 10,30,50,100,120 & 500 Capsules.

MFG. IN INDIA BY:

TAJ PHARMACEUTICALS LTD.

at: Tal - Sanand Dist. Ahmedabad, Gujarat (India)

MFG. Licence No. : xx.xxx

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

This leaflet was last revised in May 2018.

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