

PRESCRIBING INFORMATION

SIALOR[®]

(Anetholtrithion)

25mg Tablets

Sialogogue

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(Anetholtrithion)

25mg Tablets

THERAPEUTIC CLASSIFICATION

Sialogogue

ACTION AND CLINICAL PHARMACOLOGY

In addition to its choleric activity, anetholtrithion has a positive effect on drug induced asialias which may be due to the drug's direct action on the secretory cells of the salivary glands.

Approximately 30% of an orally administered dose is absorbed from the gastrointestinal tract, with 80% being excreted in the urine and the remainder in the bile.

In man, the average amounts of anetholtrithion recovered as the free

p-hydroxyphenyltrithione metabolite or its o-glucuronide are 1.5 to 3 and 12%, respectively. The yellow colouration of the urine resulting from anetholtrithion ingestion is due to the presence of the 2 metabolites.

INDICATIONS

The treatment of oral symptoms of xerostomia in order to reverse drug-induced hyposialosis related to the administration of certain drugs (neuroleptics, tranquilizers, antidepressants, synthetic antiparkinsonian agents) or following a course of radiotherapy of the head and neck area.

CONTRAINDICATIONS

Jaundice, cirrhosis, biliary tract or common bile duct obstruction.

PRECAUTIONS

Rarely, soft stools may be produced. If this persists, reduce the dosage to 25 mg in the morning and 25 mg in the evening.

Pregnancy and Lactation:

Anetholtrithion's safety for use in human pregnancy has not been established. Therefore, the drug should not be used in pregnancy or lactation unless its use is deemed essential to the welfare of the mother and/or fetus.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

Symptomatic: gastric lavage, induce diuresis.

DOSAGE AND ADMINISTRATION

25 mg 3 times a day before meals. Treatment may be continuous or intermittent with 5 drug free days/month in association with the drugs responsible for the asialia. In hyposialosis related to radiotherapy, administration may be continued indefinitely. Usually, anetholtrithion's full therapeutic effect is gradually achieved after several days of treatment.

AVAILABILITY

Each orange-red, sugar coated tablet contains: anetholtrithion 25 mg. Sunset Yellow and Carmine Red dyes are used in the tablet coating. Boxes of 60.