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Gold Sodium Thiomalate

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Pronunciation

(gold SOW dee um thye oh MAL ate)

Index Terms

- Sodium Aurothiomalate

Pharmacologic Category

- Gold Compound

Pharmacology

Unknown, may decrease prostaglandin synthesis or may alter cellular mechanisms by inhibiting sulfhydryl systems

Excretion

Urine (60% to 90%); feces (10% to 40%)

Onset of Action

Delayed; may require up to 6 months

Half-Life Elimination

6 to 25 days; may be prolonged with multiple doses

Use: Labeled Indications

Rheumatoid arthritis: Adjunctive treatment of active rheumatoid arthritis.

Juvenile rheumatoid arthritis: Adjunctive treatment of juvenile rheumatoid arthritis.

Contraindications

Hypersensitivity to gold compounds or any component of the formulation; systemic lupus erythematosus; blood dyscrasias or a history of agranulocytosis, hemorrhagic diathesis or drug-induced granulocytopenia or anemia; renal disease; hepatic impairment; history of severe adverse effects with previous gold therapy (eg, bone marrow aplasia or other hematological disorders, exfoliative dermatitis, necrotizing enterocolitis, pulmonary fibrosis); significant dermatitis, including urticaria or eczema; pregnancy; breastfeeding.

Dosing: Adult

Rheumatoid arthritis: IM: 10 mg first week; 25 mg second week; then 25 to 50 mg/week for an additional 20 weeks or until development of toxicity. For patients with modest improvement, a prolonged period of weekly injections may be maintained. For patients with a good to excellent response, continue 50 mg tapered progressively to every 2 to 4 weeks based on tolerability and response.

Dosage adjustment for concomitant therapy: Significant drug interactions exist, requiring dose/frequency adjustment or avoidance. Consult drug interactions database for more information.

 [Detailed Gold sodium thiomalate dosage information](#)

Dosing: Geriatric

Refer to adult dosing.

Dosing: Pediatric

Rheumatoid arthritis: IM: Initial: Test dose of 10 mg is recommended, followed by 1 mg/kg/week (maximum: 50 mg/injection); maintenance: 1 mg/kg/dose (maximum: 50 mg/injection) at every-other-week intervals for 2 to 20 weeks, then every 3 to 4 weeks. Early improvement may be observed after 6 to 8 weeks of therapy; months of therapy may be required before clinical improvement is observed.

Dosage adjustment for concomitant therapy: Significant drug interactions exist, requiring dose/frequency adjustment or avoidance. Consult drug interactions database for more information.

Dosing: Adjustment for Toxicity

Mild to moderate reactions: Temporarily interrupt therapy; may be cautiously resumed 2 or 3 weeks after reaction has subsided. If therapy resumed, administer a test dose of 5 to 10 mg; if the test dose is tolerated, therapy may be cautiously continued in larger doses on subsequent injections at a decreased frequency.

Severe reactions: Permanently discontinue therapy.

Administration

IM: Deep IM injection into the upper outer quadrant of the gluteal region. Observe patient for 30 minutes after

administration for anaphylactic reaction.

Storage

Store at 15°C to 30°C (59°F to 86°F). Protect from light. Should not be used if solution is darker than pale yellow.

Drug Interactions

Angiotensin-Converting Enzyme Inhibitors: May enhance the adverse/toxic effect of Gold Sodium Thiomalate. An increased risk of nitritoid reactions has been appreciated. *Monitor therapy*

Aspirin: May enhance the adverse/toxic effect of Gold Sodium Thiomalate. Specifically, liver function tests may be elevated when these agents are combined. *Monitor therapy*

PenicillAMINE: Gold Sodium Thiomalate may enhance the adverse/toxic effect of PenicillAMINE. Specifically, this combination may increase the risk for serious hematologic and/or renal adverse reactions. *Avoid combination*

Phenylbutazone: May enhance the adverse/toxic effect of Gold Sodium Thiomalate. Specifically, the risk for hematologic adverse effects may be increased. *Monitor therapy*

 [Gold sodium thiomalate drug interactions](#) (more detail)

Adverse Reactions

The following adverse drug reactions and incidences are derived from product labeling unless otherwise specified.

>10%:

Dermatologic: Skin rash (30%)

Gastrointestinal: Mucous membrane lesion (20%)

Genitourinary: Proteinuria (10% to 15%)

1% to 10%: Hematologic & oncologic: Thrombocytopenia (1% to 3%), leukopenia (2%)

Frequency not defined:

Cardiovascular: Bradycardia, syncope, vasomotor symptoms (nitritoid reaction)

Central nervous system: Encephalitis, encephalopathy, Guillain-Barre syndrome, metallic taste, peripheral neuropathy

Dermatologic: Alopecia, blue-gray skin pigmentation (chrysiasis, irreversible), bullous dermatitis, erythema of skin, exfoliative dermatitis, pruritus

Endocrine & metabolic: Albuminuria

Gastrointestinal: Diarrhea, enterocolitis, stomatitis

Genitourinary: Nephrotic syndrome

Hematologic & oncologic: Agranulocytosis, aplastic anemia, eosinophilia, neutropenia, pancytopenia

Hepatic: Cholestatic jaundice, hepatotoxicity

Hypersensitivity: Anaphylaxis, angioedema, nonimmune anaphylaxis, tongue edema

Neuromuscular & skeletal: Arthralgia

Ophthalmic: Corneal deposits (gold)

Renal: Acute renal failure

Respiratory: Interstitial pulmonary disease, pulmonary fibrosis, pulmonary infiltrates

 [Gold sodium thiomalate side effects](#) (more detail)

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Warnings/Precautions

Concerns related to adverse effects:

- Dermatologic reactions: Dermatitis and lesions of the mucous membranes are common and may be serious; pruritus may precede the early development of a skin reaction. Consider alternative therapy in patients with dermatitis; may increase risk and/or symptoms of gold toxicity may be more difficult to detect. Use is contraindicated in patients with significant dermatitis, including urticaria or eczema.
- GI effects: Signs of toxicity include persistent diarrhea, stomatitis, and enterocolitis; avoid use in patients with prior inflammatory bowel disease.
- Hematologic effects: Signs of toxicity include hematologic depression (depressed hemoglobin, eosinophilia, leukocytes, granulocytes, or platelets). Use is contraindicated in patients with a history of blood dyscrasias or a history of agranulocytosis, hemorrhagic diathesis, or drug-induced granulocytopenia or anemia. Symptoms of gold toxicity may be

difficult to detect in patients with prior abnormalities; consider alternative therapy.

- **Hepatic effects:** May be associated with the development of cholestatic jaundice. Use is contraindicated in patients with hepatic impairment.
- **Hypersensitivity reactions:** Rare hypersensitivity reactions, including anaphylactic shock, syncope, bradycardia, thickening of the tongue, difficulty in swallowing and breathing, and angioedema have been reported in association with injections of sodium aurothiomalate; treatment should be discontinued if these reactions occur. In addition, a vasomotor (nitritoid) reaction characterized by acute flushing and tachycardia may occur within minutes of injection; this reaction should be differentiated from anaphylaxis and therapy may be continued, but a careful evaluation of risk versus benefit should be undertaken and extreme caution should be exercised before resuming therapy, particularly in patients with cardiovascular disease.
- **Pulmonary toxicity:** May be associated with interstitial fibrosis; monitor closely.
- **Renal effects:** Renal toxicity ranges from mild proteinuria to nephrotic syndrome. Use is contraindicated in patients with renal disease.

Disease-related concerns:

- **Cardiovascular disease:** Use caution in patients with heart failure, hypertension, or cerebrovascular disease.

Other warnings/precautions:

- **Administration:** Must not be injected IV.
- **Experienced physician:** Physicians should be experienced with chrysotherapy and should be familiar with the toxicity and benefits of therapy.
- **Monitoring:** Frequent monitoring of patients for signs and symptoms of toxicity will prevent serious adverse reactions.

Monitoring Parameters

CBC with differential, platelet count, hemoglobin determination, and urinalysis for protein, white cells, red cells, and casts, at baseline and prior to each injection. Skin and oral mucosa should be inspected for skin rash, bruising, or oral ulceration/stomatitis. Specific questioning for symptoms such as pruritus, rash, stomatitis or metallic taste should be included.

Reproductive Considerations

Females of childbearing potential should be instructed to avoid pregnancy.

Pregnancy Considerations

Gold crosses the placenta and accumulates in the fetus.

Use is contraindicated during pregnancy.

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Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

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DRUG STATUS

Availability

 Discontinued

Pregnancy & Lactation

 Risk data available

CSA Schedule*

N/A Not a controlled drug



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