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Bicillin L-A Injectable in Tubex (Penicillin G Benzathine Injectable in Tubex)

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As with other penicillins, untoward reactions of the sensitivity phenomena are likely to occur, particularly in individuals who have previously demonstrated hypersensitivity to penicillins or in those with a history of allergy, asthma, hay fever, or urticaria.

As with other treatments for syphilis, the Jarisch-Herxheimer reaction has been reported.

The following have been reported with parenteral penicillin G:

Hypersensitivity reactions including the following: skin eruptions (maculopapular to exfoliative dermatitis), urticaria, laryngeal edema, fever, eosinophilia; **General:** other serum sickness-like reactions (including chills, fever, edema, arthralgia, and prostration); and anaphylaxis including shock and death. Note: Urticaria, other skin rashes, and serum sickness-like reactions may be controlled with antihistamines and, if necessary, systemic corticosteroids. Whenever such reactions occur, penicillin G should be discontinued unless, in the opinion of the physician, the condition being treated is life-threatening and amenable only to therapy with penicillin G. Serious anaphylactic reactions require immediate emergency treatment with epinephrine. Oxygen, intravenous steroids, and airway management, including intubation, should also be administered as indicated.

WARNINGS symptoms may occur during or after antibacterial treatment. (See *pseudomembranous colitis*. Onset of *Pseudomembranous colitis* **Gastrointestinal:** section.)

Hemolytic anemia, leukopenia, thrombocytopenia. **Hematologic:**

Neuropathy. **Neurologic:**

Nephropathy. **Urogenital:**

The following adverse events have been temporally associated with parenteral administration of penicillin G benzathine:

Hypersensitivity reactions including allergic vasculitis, pruritus, fatigue, asthenia, and pain; aggravation of existing disorder; headache. **Body as a Whole:**

Cardiac arrest; hypotension; tachycardia; palpitations; pulmonary hypertension; pulmonary embolism; vasodilation; vasovagal reaction; **Cardiovascular:** cerebrovascular accident; syncope.

Nausea, vomiting; blood in stool; intestinal necrosis. **Gastrointestinal:**

Lymphadenopathy. **Hemic and Lymphatic:**

Injection site reactions including pain, inflammation, lump, abscess, necrosis, edema, hemorrhage, cellulitis, hypersensitivity, atrophy, ecchymosis, **Injection Site:** and skin ulcer.

Neurovascular reactions including warmth, vasospasm, pallor, mottling, gangrene, numbness of the extremities, cyanosis of the extremities, and neurovascular damage.

Elevated BUN, creatinine, and SGOT. Musculoskeletal: Joint disorder; periostitis; exacerbation of arthritis; myoglobinuria; rhabdomyolysis. **Metabolic:**

Nervousness; tremors; dizziness; somnolence; confusion; anxiety; euphoria; transverse myelitis; seizures; coma. A syndrome manifested by a **Nervous System:** variety of CNS symptoms such as severe agitation with confusion, visual and auditory hallucinations, and a fear of impending death (Hoigne's syndrome), has been reported after administration of penicillin G procaine and, less commonly, after injection of the combination of penicillin G benzathine and penicillin G procaine. Other symptoms associated with this syndrome, such as psychosis, seizures, dizziness, tinnitus, cyanosis, palpitations, tachycardia, and/or abnormal perception in taste, also may occur.

Hypoxia; apnea; dyspnea. Skin: Diaphoresis. Special Senses: Blurred vision; blindness. Urogenital: Neurogenic bladder; hematuria; proteinuria; renal **Respiratory:** failure; impotence; priapism.

