

**VANCOUVER GENERAL HOSPITAL
CSU PHARMACEUTICAL SCIENCES
NON-FORMULARY DRUG DATA SHEET**

DRUG NAME Erwinia L-asparaginase	ALTERNATE NAME Crisantaspace, Erwinase®
MANUFACTURER EUSA Pharma	
STRENGTH 10,000 units	DOSAGE FORM vial

INDICATIONS

- Used in combination with other antineoplastic agents to induce remission in patients with ALL
- Used to treat patients who have developed hypersensitivity to L-asparaginase derived from E. coli.

DOSAGE AND ADMINISTRATION

- Recommended to be given IM/SC (lower incidence of anaphylaxis and few complications), however can be administered direct IV
- For the Adult ALL 13-01 Protocol, use after a documented severe hypersensitivity reaction to E. coli asparaginase. May be considered for mild hypersensitivity reaction to E. coli asparaginase in some circumstances.

Dose: 12,500 units/m² IM twice weekly to complete 30 weeks of asparaginase therapy

PREPARATION INSTRUCTIONS: (DO NOT use sterile water)

- Reconstitute vial with 1 to 2mL sodium chloride 0.9% solution by directing the solution against the inner vial wall slowly (DO NOT direct the solution directly onto the powder)

Volume of NS for reconstitution	Final concentration
1mL	10,000 units/mL
2mL	5,000 units/mL

- Dissolve by gentle mixing or swirling (to avoid formation of bubbles) with the vial in an upright position to minimize contact of the solution with the stopper (DO NOT vigorously shake the vial as loss of enzymatic potency may result)
- The solution should be clear & colourless. Do not use if cloudy or particles are present.
- Stability: 15 minutes in original vial and 4 hours in polypropylene or glass syringe (room temperature)

KNOWN SIDE EFFECTS*

- Allergic reactions (skin rashes, urticaria, arthralgia, respiratory distress, acute anaphylaxis), sepsis hepatotoxicity, severe pancreatitis, hyperglycemia, hypofibrinogenemia and depression of various other clotting factors (bleeding), decrease in circulating platelets, CNS effects (depression, somnolence, fatigue, coma, confusion, agitation and hallucinations), Parkinson-like syndrome (tremor and progressive increase in muscular tone), increase in blood ammonia, chills, fever, nausea, vomiting, anorexia, abdominal cramps, weight loss, headache, and irritability, azotemia, acute renal shut-down and fatal renal insufficiency, proteinuria, liver function abnormalities (elevations of AST, ALT, alkaline phosphates, bilirubin [direct & indirect] and depression of serum albumin, cholesterol and plasma fibrinogen), increases and decreases of total lipids, malabsorption syndrome & bone marrow depression

SPECIAL PRECAUTIONS ***Use CYTOTOXIC precautions***

- Store unreconstituted product in the refrigerator (2-8° C)
- Do not mix with other drugs prior to administration
- When given by IM or SC routes, the injectable volume of drug at a single site should be limited to 2mL. If a volume greater than 2mL is to be administered, use additional injection sites
- Contraindicated in patients with previous anaphylactic or hypersensitivity reactions to Erwinia asparaginase or in patients with past or present pancreatitis
- Risk of anaphylactic reactions may be significantly greater in patients who have reacted to E.coli derived asparaginase and related to the total number of doses given
- Should not be administered to women who are or are likely to become pregnant
- Liver function tests should be performed periodically during therapy
- May interfere with the enzymatic detoxification of other drugs particularly in the liver
- Frequent serum amylase determinations should be obtained to detect early evidence of pancreatitis

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***REPORT ANY ADVERSE DRUG REACTIONS TO CSU PHARMACEUTICAL SCIENCES**