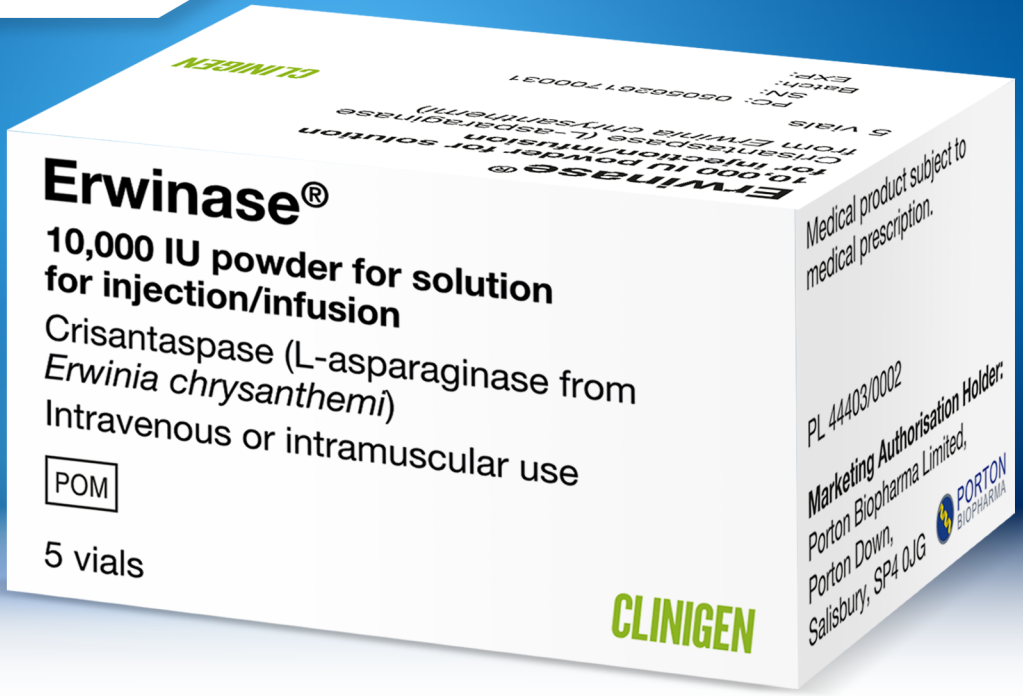
ERWINASE®

CRISANTASPASE

10,000 IU/vial Erwinia L-asparaginase



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ERWINASE 10000 IU, powder for solution for injection/infusion - Brief summary of product characteristics.
Crisantaspase (L-asparaginase from Erwinia chrysanthemi), 10,000 U/vial. **Therapeutic indications:** ERWINASE is used in combination with other chemotherapeutic agents for the treatment of patients, primarily pediatric, with acute lymphoblastic leukemia who have hypersensitivity (clinical allergy or silent inactivation) to native or pegylated asparaginase derived from E. coli appeared. **Dosage:** The recommended dosage is 25,000 IU/m² IM or IV three times per week (Monday, Wednesday and Friday) for two weeks to replace each dose of pegaspargase or each cycle of asparaginase treatment. Treatment can be adapted according to local protocol. The optimal dose of ERWINASE may vary between patients due to the high interindividual variability of the average asparaginase activity observed in pediatrics, it may therefore be advisable to monitor the asparaginase concentration with the aim of individualizing the dosage. **Method of administration:** ERWINASE solution may be administered by intravenous infusion or intramuscular injection. For intravenous infusion, it is recommended to dilute the reconstituted ERWINASE solution in 100 ml of isotonic sodium chloride and administer over 1 to 2 hours. For instructions on reconstitution and dilution of the drug before administration, **Contraindications:** History of severe hypersensitivity to the active substance or any of the excipients, Severe hepatic impairment, Current or previous severe pancreatitis associated with treatment with L-asparaginase. Current pancreatitis not associated with L-asparaginase treatment. **Interactions with other medicinal products and other forms of interactions:** No formal interaction studies have been performed. **Fertility, pregnancy and breastfeeding:** To find out the effects of co-administered chemotherapy, refer to the SmPC of the chosen chemotherapy. **Pregnancy:** There are few or limited data on the use of L-asparaginase in pregnant women, ERWINASE is not recommended during pregnancy and in women of childbearing age or men wishing to conceive a child who is not do not use contraception unless clearly indicated. **Breastfeeding:** It is not known whether L-asparaginase is excreted in human milk. The excretion of L-asparaginase in milk has not been studied in animals. A risk for breastfed children cannot therefore be excluded; ERWINASE should not be used during breastfeeding. **Adverse reactions:** Most common adverse reactions (incidence 1% or greater) are: systemic hypersensitivity, hyperglycemia, transaminases abnormal, fever, pancreatitis, local reactions, vomiting, nausea, thrombosis, hyperbilirubinemia, abdominal pain/discomfort, and diarrhea. **Reporting of suspected adverse reactions:** Reporting of suspected adverse reactions after authorization of the medicinal product is important. It allows continuous monitoring of the benefit/risk ratio of the drug. **Healthcare professionals report any suspected adverse reactions via the national reporting system:** National Agency for the Safety of Medicines and Health Products (ANSM) and network of Regional Pharmacovigilance Centers - Website: www.signallement-sante.gouv.fr. **Overdose:** There is no known antidote for asparaginase overdose. No data is available on the elimination (peritoneal or by hemodialysis) of the product. Patients who have received an accidental overdose of L-asparaginase should be closely monitored and given symptomatic treatment. An overdose of L-asparaginase can cause chronic poisoning characterized by impaired liver or kidney function. **Pharmacotherapeutic group:** Other antineoplastic agents, **ATC code:** L01XX02. **List of excipients:** Glucose monohydrate, Sodium chloride, Sodium hydroxide, Acetic acid. **MARKETING AUTHORIZATION HOLDER:** Porton Biopharma Limited, Manor Farm Road, Porton Down, Salisbury, SP4 OJG, United Kingdom.

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PORTON BIOPHARMA
www.portonbiopharma.com

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Payk Daru Tosseh Co.
(P.J.S)