Eribulin

Solution for Injection

MADE IN GERMANY

0.88 mg
2 ml

Eribulin EVER Pharma is available in a 2 ml presentation.

Indicated for the treatment of locally advanced or metastatic breast cancer, and of unresectable liposarcoma in adult patients previously treated with anthracycline-based therapy.

- **Supplied in CytoWrap®** – for safer handling and transportation

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Indications

Indicated for the treatment of adult patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting unless patients were not suitable for these treatments.

For the treatment of adult patients with unresectable liposarcoma who have received prior anthracycline containing therapy (unless unsuitable) for advanced or metastatic disease.

Active Ingredient

Eribulin mesylate

Excipients

Ethanol anhydrous, Hydrochloric acid, Sodium hydroxide, Water for injections

Presentations

- **0.88 mg/2 ml** solution for injection

Strengths

Each 1 ml contains eribulin mesylate equivalent to 0.44 mg eribulin.

Stability

- **Unopened:** 36 months. Do not store above 30°C.
- **In-use (undiluted):** 8 hours at 15-25°C (ambient lighting) and up to 32 hours at 2-8°C.
- **After dilution:** 8 hours at 15-25°C (ambient lighting) and up to 48 hours at 2-8°C.

Primary Packaging

Type I colourless glass vial with a rubber stopper, sealed with an aluminium crimp cap, covered with a plastic flip-off cap.

Pack sizes

1 vial per pack. Vials may be sheathed in a protective sleeve.

Density

0.993 g/cm^3

Cyto Wrap®

Plastic sleeving for safer handling

Eribulin EVER Pharma 0.44 mg/ml solution for injection. Composition: One ml contains eribulin mesilate equivalent to 0.44 mg eribulin. List of excipients: Ethanol anhydrous, Water for injections, Hydrochloric acid, Sodium hydroxide. Therapeutic indications: For the treatment of adult patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting unless patients were not suitable for these treatments. For the treatment of adult patients with unresectable liposarcoma who have received prior anthracycline containing therapy (unless unsuitable) for advanced or metastatic disease. Contraindications: Hypersensitivity to the active substance or to any of the excipients. Breast-feeding. Side effects: very common: Neutropenia, Leukopenia, Anaemia, Decreased appetite, Peripheral neuropathy, Headache, Dyspnoea, Cough, Nausea, Constipation, Diarrhoea, Vomiting, Alopecia, Arthralgia and myalgia, Back pain, Pain in extremity, Fatigue/Asthenia, Pyrexia, Weight decreased. common: Urinary tract infection, Pneumonia, Oral candidiasis, Oral herpes, Upper respiratory tract infection, Nasopharyngitis, Rhinitis, Herpes zoster, Lymphopenia, Febrile neutropenia, Thrombocytopenia, Hypokalaemia, Hypomagnesaemia, Dehydration, Insomnia, Depression, Dysgeusia, Dizziness, Hypoaesthesia, Lethargy, Neurotoxicity, Lacrimation increased, Conjunctivitis, Vertigo, Tinnitus, Tachycardia, Hot flush, Pulmonary embolism, Oropharyngeal pain, Epistaxis, Rhinorrhoea, Abdominal pain, Stomatitis, Dry mouth Dyspepsia, Gastrooesophageal reflux disease, Abdominal distension, Aspartate aminotransferase increased, Alanine aminotransferase increased, Gamma glutamyl transferase increased, Hyperbilirubinaemia, Rash, Pruritus, Nail disorder, Night sweats, Dry skin, Erythema, Hyperhidrosis, Palmar plantar erythrodysaesthesia, Bone pain, Muscle spasms, Musculoskeletal pain, Musculoskeletal chest pain, Muscular weakness, Dysuria, Mucosal Inflammation, Peripheral oedema, Pain, Chills, Chest pain, Influenza like illness. uncommon: Sepsis, Neutropenic sepsis, Septic Shock, Deep vein thrombosis, Interstitial lung disease, Mouth ulceration, Pancreatitis, Hepatotoxicity, Angioedema, Haematuria, Proteinuria, Renal failure. rare or unknown: Disseminated intravascular coagulation, Stevens-Johnson syndrome/ Toxic epidermal necrolysis. More information available in the summary of product characteristics. Only available on prescription. Last update: March 2024. Marketing Authorisation Holder: EVER Valinject GmbH, Oberburgau 3, 4866 Unterach am Attersee, Austria. Eribulin EVER Pharma is available after patent expiry.

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