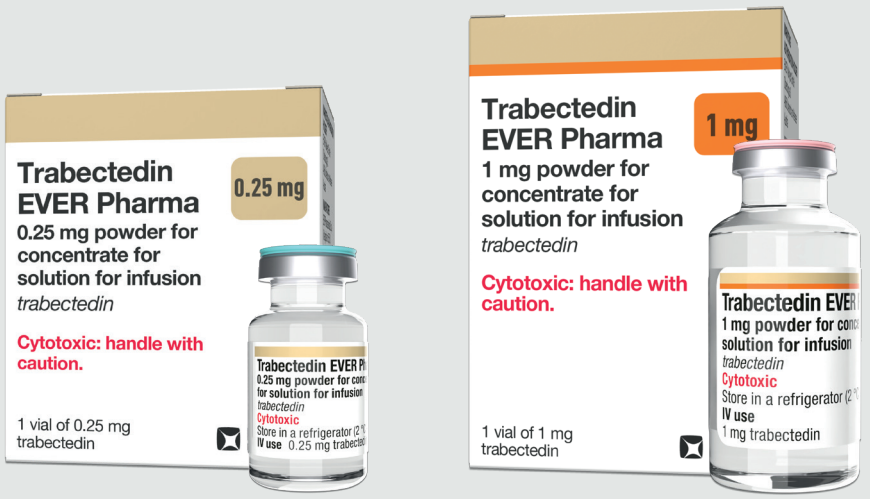
Trabectedin

MADE IN GERMANY

Powder for concentrate for solution for infusion



Trabectedin EVER Pharma is available in two presentations (0.25 mg and 1 mg), supplied in CytoWrap® for safer handling and transportation.

Indicated for the treatment of advanced soft-tissue sarcoma and, in combination with pegylated liposomal doxorubicin, for relapsed platinum-sensitive ovarian cancer.

- **Available in two presentations** – providing greater flexibility and convenience when preparing patient-specific doses
- **Supplied in CytoWrap®** – for safer handling and transportation

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Indications

Indicated for the treatment of adult patients with advanced soft tissue sarcoma, after failure of anthracyclines and ifosfamide , or who are unsuited to receive these agents.

In combination with pegylated liposomal doxorubicin (PLD) is indicated for the treatment of patients with relapsed platinum sensitive ovarian cancer.

Active Ingredient

Trabectedin

Excipients

Citric acid, L-Arginine, Phosphoric acid, Sodium hydroxide

Presentations

- **0.25 mg** powder for concentrate for solution for infusion
- **1 mg** powder for concentrate for solution for infusion

Strength

After reconstitution, each 1 ml of solution contains 0.05 mg trabectedin (0.25 mg vial reconstituted in 5 ml; 1 mg vial reconstituted in 20 ml).

Stability

- **Unopened:** 36 months (1 mg) / 24 months (0.25 mg).
  Store in a refrigerator (2 °C to 8 °C).
- **Reconstituted & Diluted Solution:** Up to 30 hours at 25 °C.

Primary Packaging

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

Pack sizes

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

Density

1.004 g/cm^3 when reconstituted according to the instructions in the package insert.

Cyto Wrap®

Plastic sleeving for safer handling

Trabectedin EVER Pharma 0.25 mg powder for concentrate for solution for infusion. Trabectedin EVER Pharma 1 mg powder for concentrate for solution for infusion. Composition: One ml of reconstituted solution contains 0.05 mg of trabectedin. List of excipients: citric acid (E330); arginine; phosphoric acid, concentrated (for pH-adjustment) (E338); sodium hydroxide (for pH-adjustment) (E524). Therapeutic indications: Trabectedin. EVER Pharma is indicated for the treatment of adult patients with advanced soft tissue sarcoma, after failure of anthracyclines and ifosfamide, or who are unsuited to receive these agents. Efficacy data are based mainly on liposarcoma and leiomyosarcoma patients. Trabectedin EVER Pharma in combination with pegylated liposomal doxorubicin (PLD) is indicated for the treatment of patients with relapsed platinum-sensitive ovarian cancer. Contraindications: hypersensitivity to trabectedin or to any of the excipients, concurrent serious or uncontrolled infection, breast-feeding, combination with yellow fever vaccine. Side effects: very common: neutropenic infection, neutropenia, thrombocytopenia, anaemia, leukopenia, decreased appetite, headache, dyspnoea, cough, abdominal pain, nausea, vomiting, constipation, diarrhoea, stomatitis, alanine aminotransferase increased, aspartate aminotransferase increased, blood alkaline phosphatase increased, blood bilirubin increased, palmar-plantar erythrodysaesthesia syndrome, back pain, blood creatine phosphokinase increased, fatigue, pyrexia, oedema, mucosal inflammation, blood creatinine increased, blood albumin decreased; common: sepsis, febrile neutropenia, hypersensitivity, dehydration, hypokalaemia, insomnia, dizziness, dysgeusia, peripheral sensory neuropathy, syncope, palpitations, left ventricular dysfunction, hypotension, flushing, pulmonary embolism, dyspepsia, gamma-glutamyltransferase increased, rash, alopecia, skin hyperpigmentation, arthralgia, myalgia, injection site reactions, weight decreased; uncommon: septic shock, capillary leak syndrome, pulmonary oedema, rhabdomyolysis, extravasation, soft tissue necrosis; rare: hepatic failure. More information is available in the summary of product characteristics. Only available on prescription. Last update: February 2023. Pharmacotherapeutic group: Antineoplastic agent, Marketing Authorisation Holder: EVER Valinject GmbH, Oberburgau 3, 4866 Unterach am Attersee. Austria.

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