Trabectedin

Powder for concentrate for solution for infusion

Trabectedin EVER Pharma is available in both 0.25 mg and 1 mg vial sizes.

Trabectedin is an antineoplastic chemotherapy drug. It is indicated as a monotherapy for the treatment of advanced soft tissue sarcoma, after failure of anthracyclines and ifosfamide, or for patients who are unsuited to receive these agents. It is also indicated in combination with pegylated liposomal doxorubicin for the treatment of relapsed platinum sensitive ovarian cancer.

- **Available in 2 presentations** – providing greater flexibility and convenience when preparing patient specific doses
- **All vial sizes come in CytoWrap®** – for safer handling and transportation

CytoWrap®
Plastic sleeving for safer handling

EVER PHARMA

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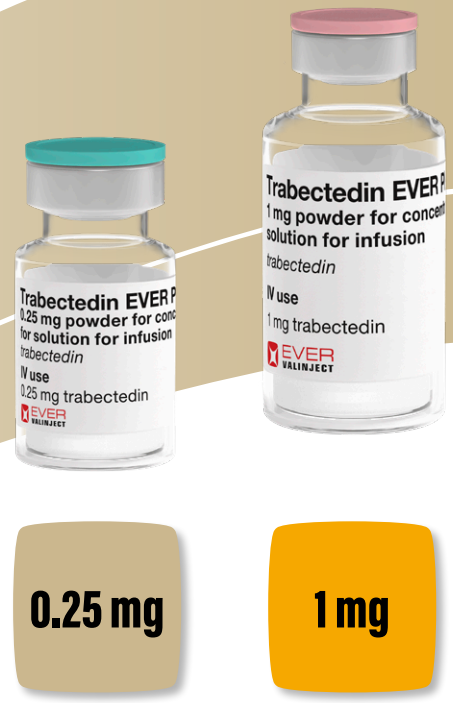

Indications

- 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.
- Trabectedin EVER Pharma 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, Arginine, Phosphoric acid, Sodium hydroxide

Primary Packaging Type I colourless glass vial with a fluoropolymer coated butyl rubber stopper sealed with an aluminium crimp cap covered with a plastic flip off cap

Presentations 0.25 mg, 1 mg

Strength After reconstitution, one ml of reconstituted solution contains 0.05 mg of trabectedin

Stability

Unopened 24 months. Store in refrigerator (2°C - 8°C)

After reconstitution 30 hours up to 25°C

After dilution 30 hours up to 25ºC

Pack sizes 1 Vial per Pack
Vials may or may not be sheathed in a protective sleeve

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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